UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

STEVEN FOSTER, individually and on behalf of all others similarly situated, Plaintiff, v. LIVANOVA PLC, SORIN GROUP DEUTSCHLAND GMBH, and SORIN GROUP USA, INC., Defendants.	)	Case No.: JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff Steven Foster, individually and on behalf of all similarly situated persons, by and through his undersigned attorneys, alleges the following upon information and belief, except for those allegations pertaining to Plaintiff, which are based on personal knowledge.

NATURE OF THE ACTION

1. Plaintiff brings this action individually and on behalf of all persons similarly situated in the South Carolina who were unknowingly exposed to potentially fatal bacteria during open chest surgery.

2. Plaintiff and the Class Members were exposed to nontuberculous mycobacterium ("NTM") through a Sorin 3T Heater-Cooler System (the "Sorin 3T System") used to regulate their blood temperature during open chest surgeries at Greenville Health Hospital System ("Greenville Health") and Palmetto Health Richland Hospital ("Palmetto Health").

3. As further described below, Defendants LivaNova PLC, Sorin Group Deutschland GmbH, and Sorin Group USA, Inc. knew or should have known that design and/or manufacturing

defects in their Sorin 3T System cause bacterial colonization to which patients are exposed during surgery, thus posing a significant risk of bodily injury or death. Additionally, Defendants knew or should have known of proper disinfectant and sterilization procedures to clean the Sorin 3T System to prevent the colonization and spreading of NTM bacteria.

4. Through this action, Plaintiff and the Class seek damages for their existing injuries and medical monitoring to screen for NTM infection, and pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*., seek a declaration that the Sorin 3T System was and is defective and unsafe for its intended use.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to the diverse citizenship of the parties. 28 U.S.C. § 1332(a)(2). Plaintiff is a citizen and resident of the State of South Carolina. Defendant LivaNova PLC is a foreign corporation incorporated under the laws of England and Wales with a corporate headquarters in Milan, Italy. Defendant Sorin Group Deutschland GmbH is a foreign corporation headquartered in Munich, Germany. Defendant, Sorin Group USA, Inc. is the U.S. distributor of the medical device at issue, with a principal place of business in Arvada, Colorado. The amount in controversy exceeds $75,000.

6. This Court additionally has subject matter over this action pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d). There are hundreds of putative class members who are or were citizens of South Carolina at the time of their exposure, and Defendants are each citizens of another state and/or a foreign country. The aggregate of the Class Members' claims is more than $5 million dollars, exclusive of interests and costs.

7. This Court has personal jurisdiction over this action pursuant to Fed. R. Civ. P. 4 and S.C. Code Ann. § 36-2-803. Defendants are non-domiciliaries of South Carolina, contract business

within South Carolina, and maintain general and specific contacts in South Carolina. Defendants have committed tortious acts within South Carolina causing injury to persons within South Carolina. Defendants solicit business and engage in persistent courses of conduct and derive substantial revenue from goods used and services rendered in South Carolina. Defendants are in the business of researching, designing, developing, testing, manufacturing, distributing, licensing, labeling, and marketing, either directly or indirectly through third-party related entities, the Sorin 3T System in South Carolina.

8. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because a substantial part of the events and/or omissions giving rise to the Plaintiff's claims emanated from activities within this jurisdiction, and Defendants conduct substantial business within this District.

THE PARTIES

9. Plaintiff is a resident and citizen of South Carolina residing in Columbia, SC. On March 13, 2014, Plaintiff underwent open heart surgery at Palmetto Health Richland Hospital ("Palmetto Health"). Because of the use of the Sorin 3T System during his surgery, Plaintiff was exposed to NTM.

10. Defendant LivaNova PLC ("LivaNova") is a foreign for-profit corporation incorporated under the laws of England and Wales with a headquarters in Milan, Italy. LivaNova is a global medical device company specializing in, among other products, devices used in the treatment of cardiovascular diseases. LivaNova, pursuant to a merger agreement between Sorin Group S.p.A.[1] and non-party, Cybertronics, Inc., advised purchasers in the United States that it is the responsible party for Sorin 3T System. Further, LivaNova was the recipient of various communications from the FDA regarding safety concerns about the Sorin 3T System.

[1] Upon information and belief, Sorin Group S.p.A. was the original holding company of Defendants Sorin Group Deutschland GmbH and Sorin Group USA, Inc.

11. Defendant Sorin Group Deutschland GmbH ("Sorin") is a foreign for-profit corporation headquartered in Munich, Germany. Sorin designed, manufactured, and marketed the Sorin 3T System used in Plaintiff's and Class Members' surgeries. In October 2015, Sorin merged with and into LivaNova, with LivaNova continuing as the surviving company.

12. Defendant Sorin Group USA, Inc. ("Sorin USA") is a U.S. designer, manufacturer, marketer, and distributor of the Sorin 3T System, with a principal place of business in Arvada, Colorado. As set forth in LivaNova's Form 10-Q filed with the Security and Exchange Commission, Defendants Sorin and Sorin USA are wholly owned subsidiaries of LivaNova. Each Defendant markets and sells products under the LivaNova name.

GENERAL FACTUAL ALLEGATIONS

A. The Sorin 3T System

13. Defendants market and sell thermal regulator devices to be used on patients in the operating room, including the Sorin 3T System.

14. Prior to May 5, 2014, the Defendants manufactured, introduced, and/or delivered for introduction into interstate commerce, the Sorin 3T System.

15. The Sorin 3T System used at Greenville Health and Palmetto Health during the relevant time period was designed, manufactured, marketed, and/or sold by Defendants LivaNova, Sorin, and Sorin USA to Greenville Health and Palmetto Health in South Carolina.

16. The Sorin 3T System is intended to provide temperature-controlled water to heat exchanger devices (cardio-pulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient during cardio-pulmonary bypass procedures lasting six (6) hours or less. The Sorin 3T System is a Class II Medical Device that is subject to the Food and Drug Administration's ("FDA") Section 510K premarket notification process ("510K" or

"510K process").[2]

17. Before commercial distribution in the United States of the Sorin 3T System, the Defendants submitted a 510K premarket notification of intent to market the Sorin 3T System with the Secretary of Health and Human Services for FDA approval. The FDA determined that the Sorin 3T System was substantially equivalent to legally marketed predicate devices that do not require approval of a premarket approval ("PMA") application. This determination was relayed to the Defendants via letter on June 6, 2006, 510K number K052601.[3] Essentially, the 510k process differs from the PMA process in how carefully the FDA examines the safety of the medical device. The PMA process is required for Class III medical devices while Class I and Class II predicate medical devices can be approved through the less rigorous 510K process.

18. The FDA approval allows the Defendants to commercially distribute the Sorin 3T System in accordance with the conditions and regulations described in the approval letter. Any commercial distribution of the Sorin 3T System that does not comply with the conditions set forth in the letter are violations of the Federal Food, Drug, and Cosmetic Act ("the Act"). Generally, the manufacturer must comply with all of the Act's requirements, including but not limited to: "Registration and Listing (21 C.F.R. part 807); Labeling (21 C.F.R. part 801); Good Manufacturing Practice Requirements as set forth in the Quality Systems Regulation (21 C.F.R. part 820); and if applicable, the Electronic Product Radiation Control Provisions (Sections 531-542 of the Act); 21 C.F.R. 1000-1050."

[2] A 510K premarket notification is a premarket submission made to the FDA to establish that the device to be marketed is substantially equivalent to a legally marketed device that is not subject to premarket approval (PMA). 21 C.F.R. 807.92(a)(3).
[3] The FDA Determination Letter of Approval is attached as Exhibit A.

B. Two South Carolina Hospitals Announce Patient Exposure to Deadly Bacteria

19. On or about June 20, 2014, Greenville Health publically announced that approximately 14 patients had tested positive for a rare nontuberculosis mycobacterium infection, known as Mycobacterium abscessus ("*M. abscessus*"). The majority of those patients were exposed to the bacterium during open chest surgeries. At that time, Greenville Health indicated that there had been three (3) deaths resulting from the same infection. On or about June 26, 2014, Greenville Health released a second statement indicating that there were 15 confirmed cases of patients with the infection. On July 21, 2014, Greenville Health confirmed that the patient death toll had increased to four (4).

20. In the July 21, 2014 announcement, Greenville Health stated that it sent out letters to "…approximately 180 patients on whom specific cardiopulmonary surgical equipment had been used" since those patients were at risk after potentially being exposed to the *M. abscessus* bacterium.[4]

21. On or about December 16, 2016, Palmetto Health announced that hundreds of its patients were exposed to rare and potentially fatal bacteria during open chest surgeries.

22. According to Palmetto Health, those at risk include patients who underwent open chest surgery at its facility during the last four years.

23. Palmetto Health sent letters to individual patients that informed them of the exposure and advised them to follow up with their physicians.[5]

C. The Fatal Bacteria

24. The bacteria at issue, known as nontuberculous mycobacterium ("NTM"), occurs naturally in the environment. Because the Sorin 3T System aerosolized NTM into the operating room during open chest surgeries, patients were exposed to a greater amount of NTM than naturally

[4] The letter sent to patients by Greenville Health is attached as Exhibit B.
[5] The letter sent to Plaintiff by Palmetto Health is attached as Exhibit C.

occurring background levels.

25. If allowed within the operative field, NTM poses a significant health risk to surgical patients and patients with compromised immune systems.

26. Because NTM is a slow growing bacterium, it generally takes anywhere from two weeks to four years before manifestation of an NTM infection, which most commonly results in pulmonary or cardiovascular disease. The recommended monitoring period after exposure is at least four years.

27. Symptoms of an NTM infection are very general and may include any combination of the following: fever, pain, redness, heat or pus around a surgical incision, night sweats, joint pain, muscle pain, and fatigue.

28. Because NTM symptoms are non-specific and manifestation may take several weeks to several years, a patient will most likely fail to link the infection to his or her prior heart surgery, particularly as more time elapses between surgery and initial symptomatology.

29. The diagnosis of an NTM infection requires targeted culturing, molecular diagnostic testing, and/or other screening processes not performed unless physicians are acutely aware of NTM exposure.

30. Most NTM infections are naturally resistant to common antibiotics. To overcome drug resistance, it is often necessary to take several different antibiotics at the same time. Depending on the severity of the infection, treatment may be needed for as long as two years.

31. While an NTM infection diagnosed early may be successfully treated with a series of antibiotics, there is a significant risk of death in cases diagnosed late and in individuals with considerably weakened immune systems.

32. Upon information and belief, 15 individuals who underwent open chest surgery at

Greenville Health during the relevant time period have been diagnosed with a NTM infection. Of that infected group, four have died.

33. Investigations were undertaken by the South Carolina Department of Health and Environmental Control ("DHEC") in an effort to determine the cause(s) for the *M. abscessus* infection outbreak at Greenville Health. On July 21, 2014, prior to the recall on the Sorin 3T System, DHEC released a statement that outlined specific measures that needed to be immediately implemented at Greenville Health as it related to the "cardioplegia machine."

D. Medical Devices Identified as the Infection Source

34. Heater-cooler devices work by aerosolizing temperature controlled water. When the water used in the reservoir of the device contains even trace levels of NTM, the bacteria colonizes, and patients are exposed to the bacteria that are aerosolized through the device's exhaust vent.

35. The airborne transmission of NTM from contaminated heater-cooler units was recognized as a patient risk throughout Europe as early as 2011.

36. A Rapid Risk Assessment released by the European Centre for Disease Prevention and Control ("ECDC") in April 2015 notes that invasive cardiovascular infections identified as NTM have been reported in Switzerland, Germany, and the Netherlands since 2011.

37. A public health investigation in Switzerland included microbiological examinations of environmental samples that identified *M. Chimaera* (a strand of NTM) contamination in heater-cooler units, including water samples from the units. Air sampling cultures were positive for *M. chimaera* when the units were running, but negative when they were turned off.

38. In July 2015, an article was published in the Journal of Clinical Infectious Diseases following patients in Europe who contracted NTM. The article concluded that the epidemiological and microbiological features of the prolonged outbreak in Europe provided evidence of the airborne

transmission of *M. Chimaera* from contaminated heater-cooler units.

39. On October 15, 2015, the Food and Drug Administration ("FDA") issued a Safety Communication noting that between January 2010 and August 2015, the agency received 32 Medical Device Reports of patient infections associated with heater-cooler device contamination, eight in the U.S., and the remaining 24 predominantly from Western Europe.

40. On October 21, 2015, the Centers for Disease Control and Prevention ("CDC") issued an Interim Practical Guidance communication intended to raise awareness among health departments, healthcare facilities, and providers of the association between NTM infections and the use of heater-cooler devices.

E. Recall of the Sorin 3T System

41. On July 15, 2015, the FDA issued a Class II Recall of the Sorin 3T System because of "[p]otential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."[6]

42. The recall directed customers to follow the *new* cleaning and disinfection procedures outlined in a Field Safety Notice issued by LivaNova and/or Sorin on June 15, 2015 to users in European Union English-speaking countries, followed up by a similar Notice to users in the United States on August 6, 2015.[7]

43. Sorin indicated that it was providing the Field Safety Notice Letters for the following reasons.

> [To] remind [affected users] of the importance of following [the company's] disinfection and maintenance procedures.

[6] *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=138337 (last visited January 22, 2017).

[7] The June 3, 2015 Notice is attached as Exhibit D, and the August 6, 2015 Notice is attached as Exhibit E.

> [To] inform [affected users that] . . . there is a possibility that bacteria can be aerosolized when the [heater-cooler] device is operated serving as a potential source for contamination.
>
> [To] provide [affected users] with updated instructions for use regarding disinfection and maintenance procedures.[8]

44. According to this Field Safety Notice, the company's hygiene concept was "enhanced" by introducing the following modifications:

a. The use of filtered tap water when filling the device;

b. Instead of three different procedures (every five days, every two weeks, and every three months), only two different procedures (every seven days and every 14 days) to make disinfection easier;

c. The option to use peracetic acid instead of chloride solution;

d. H2O2 in low dose for preservation;

e. All external tubing, bottles, and buckets were to be included in the disinfection process;

f. The use of polyethylene tubing that meets national drinking water standards; and

g. That unused heater-coolers must be disinfected bi-weekly.

45. However, in May 2015, a month prior to the recall, LivaNova and/or Sorin determined that devices that had not been maintained according to the manufacturer's instructions for use ("IFUs") for a long period of time required a mechanical deep disinfection process to remove bacterial colonization, referred to as "biofilm".

46. Upon information and belief, LivaNova and/or Sorin knew or should have known that

[8] Exhibit E at 1.

design and/or manufacturing defects in its 3T System render it prone to bacterial colonization, *regardless of the cleaning and disinfection procedures used*.

47. The FDA recently raised significant questions about the safety and efficacy of the Sorin 3T System.

48. On December 29, 2015, the FDA issued a Warning Letter to the Defendants, which indicated that its inspection of Sorin's Germany and Colorado facilities revealed that the Sorin 3T System devices had been "adulterated," meaning the "methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation [were] not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."[9]

49. In the letter, the FDA identified various design change orders dating back to December 11, 2012 that had never been submitted to the FDA for approval.

50. The letter also identified several changes to the disinfection instructions, dating back to December 20, 2011, that had never been reported to the FDA and which, like the current disinfection instructions, lacked proper efficacy validation.

F. Patient Risk Due to Continued Use of the Sorin 3T System

51. In response to the infection outbreak, Greenville Health "instituted numerous measures focused on reducing or eliminating the levels of mycobacterium within [its] facilities."[10]

52. Palmetto Health "has created a comprehensive plan which includes changing venting of the current machines in the operating room and has ordered new machines."[11]

53. It is unknown to Plaintiff whether Greenville Health or Palmetto Health replaced their

[9] The December 29, 2015 Warning Letter is attached as Exhibit F.
[10] *See* https://www.ghs.org/upload/docs/GHSInvestigation.pdf (last visited January 17, 2017).
[11] *See* https://www.palmettohealth.org/medical-services/cardiac-services/cardiovascular-surgery/heater-cooler-faq (last visited January 22, 2017).

original 3T Systems with new 3T Systems of the same design, which are also prone to bacterial colonization and aerosolization.

54. Upon information and belief, other hospitals throughout South Carolina continue to use the Sorin 3T Heater-Cooler System, placing open chest surgery patients at significant risk of injury or death.

CLASS ACTION ALLEGATIONS

55. The Class claims all derive directly from a single course of conduct by the Defendants. The Defendants engaged in uniform and standardized conduct toward the Class. They did not differentiate, in degree of care or candor, their actions or inactions among individual Class members. The objective facts are the same for all Class members. Within each Claim for Relief, the same legal standards under South Carolina and/or federal law govern. Accordingly, Plaintiff brings this lawsuit as a class action on his own behalf and on behalf of all other persons similarly situated as members of the proposed Classes pursuant to Federal Rule of Civil Procedure 23. This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of those provisions.

Class Definition

56. Plaintiff seeks to certify a class defined as follows:

> All individuals residing in the State of South Carolina who underwent open chest surgery at Greenville Health or Palmetto Health since January 1, 2011 and who are currently asymptomatic for nontuberculous mycobacterium (or "NTM") infection.

Claims for actual injury from an NTM infection are excluded from the claims brought in this class action.

57. Plaintiff seeks to certify the above defined Class for all causes of action alleged herein.

58. The prerequisites to maintaining a class action under Fed. R. Civ. P. 23(a) and (b) are met for the following reasons.

Numerosity

59. Upon information and belief, Plaintiff states that there are hundreds or thousands of individuals who underwent open chest surgery during the relevant time periods. Therefore, the proposed Class is so numerous that joinder of all individual members is impractical.

Commonality

60. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to Plaintiff and Class Members are:

a. Whether and the degree to which they were exposed to NTM during their surgeries;

b. Whether they were exposed to NTM at rates higher than, or through a more dangerous manner than, the general population;

c. Whether the 3T System is the source of their NTM exposure;

d. Whether Defendants knew or should have known of their NTM exposure;

e. Whether their exposure to NTM was caused by the negligence of the Defendants;

f. Whether the 3T System is defectively designed;

g. Whether safer alternative designs for the 3T System existed which could have prevented the colonization and aerosolization of bacteria;

h. Whether the 3T System used in their surgeries contained manufacturing defects;

i. Whether the 3T System is unsafe for its intended use; and

j. Whether the Defendants are legally responsible for implementing and maintaining a medical monitoring fund to provide NTM screening.

Typicality

61. Plaintiff's claims are typical of the claims of Class Members because they each underwent heart surgeries at [insert hospital(s)] during the time period in which the allegedly defective medical devices were used. Plaintiff alleges that his exposure to NTM occurred in substantially the same way. As such, the claims or defenses of the representative parties are typical of the claims or defenses of the Class.

Adequacy of Representation

62. Plaintiff will fairly and adequately protect the interests of Class Members. Plaintiff has retained counsel competent and experienced in complex class action litigation and with adequate resources to assure the interests of the Class will not be harmed. The named Plaintiff is typically situated and has no conflict of interest with the Class as a whole.

Class Action Maintainable under Rule 23(b)(2)

63. A class action is appropriate because common questions of law and fact predominate over any individual questions affecting only individual class members. Class treatment is superior to the alternatives for the fair and efficient adjudication of the controversy alleged herein. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would entail. No difficulties are likely to be encountered in the management of this class action that would preclude its maintenance as a class action, and no superior alternative exists for the fair and efficient adjudication of this controversy. Without a class action, Defendants will remain free from responsibility for exposing at least [insert] patients to a potentially deadly bacterium

and Class Members, who have limited resources, will either be forced to fund their own medical screening or forgo the necessary screening due to financial constraints.

Class Maintainable under Rule 23(b)(3)

64. By negligently exposing Plaintiff and Class Members to NTM, Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making the implementation and maintenance of a medical monitoring fund and declaratory relief the appropriate remedies for the Class.

Ascertainability

65. The Class Members are ascertainable as Greenville Health and Palmetto Health can identify every single class member from their respective contemporaneously kept medical records, as evidenced by the fact that Greenville Health and Palmetto Health have sent letters to their respective patients warning them of potential exposure to NTM. Accordingly, nothing more than a ministerial act on the part of non-parties Greenville Health and Palmetto Health will be necessary to ascertain all potential Class Members.

TOLLING OF THE STATUTE OF LIMITATIONS

Discovery Rule

66. Under South Carolina law, the discovery rule tolls the statute of limitations when a plaintiff, due to facts or circumstances not within his or her control, is unable to discover his injury and its cause within the prescribed time period.

67. Under the discovery rule, the statute of limitations begins to run when a plaintiff knows, or in the exercise of reasonable diligence should have known: (1) that he or she has been injured, and (2) that his or her injury was caused by the conduct of another.

68. Prior to Greenville Health's June 20, 2014 and Palmetto Health's December 16, 2016

announcements and correspondence advising that Plaintiff and Class Members may have been exposed to NTM, Plaintiff was wholly unaware of both his exposure to NTM and the fact that his exposures may have been caused by a defective medical device.

69. Any applicable statute of limitation has therefore been tolled by Plaintiff's and Class Members' lack of knowledge of the facts alleged herein prior to June 20, 2014 and December 16, 2016.

COUNT I - NEGLIGENCE

70. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

71. Defendants owed a duty of reasonable care to the general public, including Plaintiff, when it designed, labeled, manufactured, assembled, inspected, tested, marketed, placed into the stream of commerce, instructed, and sold the Sorin 3T System, to assure that the product complied with FDA regulations and was not defective and/or unreasonably dangerous for its intended purposes and foreseeable uses.

72. Defendants breached this duty in the design, labeling, manufacturing, assembling, inspecting, testing, marketing, distributing, instructing, and selling of Sorin 3T System in a defective and unreasonably unsafe condition by, *inter alia*:

a. Failing to conduct adequate safety and efficacy testing before seeking to have the Sorin 3T System put into the stream of commerce;

b. Failing to notify the FDA of design change orders to the Sorin 3T System;

c. Supplying "validation" studies to the FDA that failed to demonstrate the safety and efficacy of cleaning and disinfection procedures for the Sorin 3T System;

d. Failing to warn Plaintiff and Class Members of the potential for bacterial colonization and patient exposure to such bacteria;

e. Designing the Sorin 3T System in such a way that it is prone to bacterial colonization and aerosolization; and

f. Failing to ensure proper workmanship, materials, and labeling for the Sorin 3T System.

73. Defendants owed Plaintiff and the Class a duty of reasonable care to discover defects and/or errors in the machine and to inform and/or warn the FDA, the medical community, Plaintiff, the Class, and the public of a defect once it was discovered. Defendants violated these duties when they failed to do so, which further placed Plaintiff and the Class Members at risk for harm and injury.

74. The Sorin 3T System differed in design, manufacture, packaging, storing, warning, labeling, instructions for use, distribution, and advertising from the system that received approval through the 510K process, and thus the design, manufacture, packaging, storing, warning, labeling, instructions for use, distribution, and advertising of the Sorin 3T System used at Greenville Health and Palmetto Health was in violation of those requirements.

75. Defendants had the duty to comply with and not deviate from statutory requirements, which amongst other things, require that the device be manufactured, labeled, and designed according to the standards set forth in the FDA approval. Defendants violated these duties when they failed to comply with and deviated from the statutory requirements.

76. As a direct and proximate result of Defendants' negligence, Plaintiff and the Class Members have suffered an injury-in-fact in the form of necessary healthcare, attention, and services, and emotional distress and anxiety resulting from knowing they have been exposed to NTM that may lead to serious illness or death, for which Plaintiff and the Class is entitled to and compensatory and punitive damages in an amount to be proven at trial.

COUNT II – STRICT PRODUCTS LIABILITY

77. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

78. Under South Carolina Code § 15-73-10, Defendants' sale of the Sorin 3T System in a defective condition or unreasonably dangerous condition, along with Defendants' violations of federal regulations as outlined herein, establish a prima facie case of strict liability in tort.

79. As a direct and proximate result of Defendants' violations, Plaintiff and the Class Members have suffered an injury-in-fact in the form of necessary healthcare, attention, and services, and emotional distress and anxiety resulting from knowing they have been exposed to NTM that may lead to serious illness or death, for which Plaintiff and the Class is entitled to and compensatory and punitive damages in an amount to be proven at trial.

COUNT III – BREACH OF EXPRESS WARRANTY

80. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

81. Defendants expressly warranted through their marketing, advertising, distributors, and sales representatives that the Sorin 3T System was of merchantable quality and fit for the ordinary purposes and uses for which it was sold.

82. Defendants breached these express warranties by designing, labeling, manufacturing, and selling the defective and unreasonably dangerous Sorin 3T System that was neither of merchantable quality nor fit for the ordinary purposes for which it was sold, presenting an unreasonable risk of injury to patients, including Plaintiff and the Class Members, during foreseeable use.

83. As a direct and proximate result of Defendants' breach of implied warranties,

Plaintiff and the Class Members have suffered an injury-in-fact in the form of necessary healthcare, attention, and services, and emotional distress and anxiety resulting from knowing they have been exposed to NTM that may lead to serious illness or death, for which Plaintiff and the Class is entitled to and compensatory and punitive damages in an amount to be proven at trial.

COUNT IV – BREACH OF IMPLIED WARRANTY

84. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

85. Defendants impliedly warranted through their marketing, advertising, distributors, and sales representatives that the Sorin 3T System was of merchantable quality and fit for the ordinary purposes and uses for which it was sold.

86. When the Sorin 3T System was used during Plaintiff's and the Class Members' heart procedures, the system was being used for the original purposes for which it was approved and intended.

87. Plaintiff and the Class Members, individually and/or by and through their healthcare providers, relied upon Defendants' implied warranties of merchantability in consenting to have the heart procedures performed with assistance of the Sorin 3T System.

88. Defendants breached these implied warranties of merchantability because the Sorin 3T System was neither merchantable nor suited for the intended uses for which it was sold.

89. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff and the Class Members have suffered an injury-in-fact in the form of necessary healthcare, attention, and services, and emotional distress and anxiety resulting from knowing they have been exposed to NTM that may lead to serious illness or death, for which Plaintiff and the Class is entitled to and compensatory and punitive damages in an amount to be proven at trial.

COUNT V – NEGLIGENT MISREPRESENTATION

90. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

91. Defendants negligently misrepresented to the FDA, the medical community, Plaintiff, the Class Members, and the public the defective nature and extent of adverse reactions and labeling errors of the Sorin 3T System.

92. Defendants failed to adhere to FDA regulations by failing to appropriately report all of the information and knowledge in their possession regarding the dangers Defendants knew their product presented, including, but not limited to, the fact that colonization of Mycobacteria inside the Sorin 3T System could occur if specific disinfection and maintenance procedures were not implemented.

93. Had Defendants accurately and truthfully represented to the FDA, the medical community, Plaintiff, the Class Members, and the public the material facts relating to the risks of the Sorin 3T System, Greenville Health and Palmetto Health would not have utilized the Sorin 3T System as they did during the procedures that caused Plaintiff's and the Class Members' injuries.

94. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff and the Class Members have suffered an injury-in-fact in the form of necessary healthcare, attention, and services, and emotional distress and anxiety resulting from knowing they have been exposed to NTM that may lead to serious illness or death, for which Plaintiff and the Class is entitled to and compensatory and punitive damages in an amount to be proven at trial.

COUNT VI – MISREPRESENTATION BY OMISSION

95. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

96. Throughout the relevant time period, Defendants knew that the Sorin 3T System was defective and unreasonably unsafe for intended purposes, which Defendants failed to properly report to the FDA, the medical community, Plaintiff, the Class Members, and the public.

97. Defendants had a duty to disclose to the FDA, the medical community, Plaintiff, the Class Members, and the public the defective nature and extent of adverse reactions and labeling errors of the Sorin 3T System, because the Defendants were in a superior position to know the true quality, safety, and efficacy of the Sorin 3T System.

98. Defendants concealed from and/or failed to disclose to the FDA, the medical community, Plaintiff, the Class Members, and the public that the Sorin 3T System was defective, unsafe, unfit for its intended uses, and not of merchantable quality.

99. The facts concealed and/or not disclosed to the FDA, the medical community, Plaintiff, the Class Members, and the public were material facts that a reasonable person would have considered important in deciding whether to utilize the Sorin 3T System.

100. As a direct and proximate result of Defendants' concealment and misrepresentations by omission, Plaintiff and the Class Members have suffered an injury-in-fact in the form of necessary healthcare, attention, and services, and emotional distress and anxiety resulting from knowing they have been exposed to NTM that may lead to serious illness or death, for which Plaintiff and the Class is entitled to and compensatory and punitive damages in an amount to be proven at trial.

COUNT VII – MEDICAL MONITORING

101. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

102. The latency period for the manifestation of an NTM infection is estimated to be between

anywhere from two weeks to five years after exposure.

103. Plaintiff and Class Members have been exposed to NTM at rates higher than, or in a substantially more dangerous manner than, the general population. Plaintiff's exposure levels are therefore substantial in nature.

104. When NTM is transmitted in the method described above, namely airborne transmission from a contaminated medical device to an individual undergoing invasive heart surgery, it is widely acknowledged as dangerous and potentially life-threatening bacteria.

105. Plaintiff's and the Class Members' exposure to NTM was proximately caused by Defendants' negligence as described herein.

106. Monitoring procedures exist that make the detection of NTM infections possible.

107. NTM infections are capable of early detection by way of existing scientific methods including, but not limited to, targeted culturing and DNA sequencing of invasive samples (*e.g.*, blood, pus, tissue biopsy, or implanted prosthetic material).

108. Because NTM screening is not conducted in the absence of exposure to NTM, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Plaintiff and Class Members require specialized screening not within the purview of routine medical exams.

109. The prescribed monitoring regime is reasonably necessary according to contemporary scientific principles in order to provide for early diagnosis of NTM infections leading to benefits in treatment, management, rehabilitation, and prevention or mitigation of long term health consequences, including death.

110. Due to the liability of Defendants as pleaded in the preceding causes of action, one element of Defendants' responsibility and of the damages sought in this case is the establishment

of a court-approved program funded by Defendants to pay for the costs of NTM screening to mitigate the risk of serious illness or death.

111. Without a medical monitoring program, Plaintiff and the Class Members might not receive prompt medical care that could prolong their productive lives, increase prospects for improvement of their quality of life, and minimize disability.

112. For the foregoing reasons, Plaintiff seeks declaratory and injunctive relief in the form of a medical monitoring program funded by Defendants for the benefit of Plaintiff and the Class Members to provide them with all future medical monitoring necessary to detect NTM.

113. In the alternative, Plaintiff seeks compensatory damages adequate to pay for such medical monitoring.

COUNT VIII – DECLARATORY RELIEF

114. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

115. Pursuant to 28 U.S.C. § 2201, a court may "declare the rights and legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

116. Declaratory relief is intended to minimize "the danger of avoidable loss and unnecessary accrual of damages." 10B Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure* § 2751 (3d ed. 1998).

117. Plaintiff alleges that the Sorin 3T System is defective in that it is prone to bacterial colonization that may be transmitted to patients during surgery.

118. There are actual controversies between Plaintiff and Defendants, concerning: (1) whether the Sorin 3T System is defective, (2) whether Defendants knew, or should have known, of defects in their Sorin 3T System, and (3) whether Defendants failed to adequately warn of the risk of

bacterial colonization in their Sorin 3T System.

119. The declaratory relief requested herein will generate common answers that will settle the controversy related to the alleged defects in the Sorin 3T System. There is an economy to resolving this issue as it has the potential to eliminate the need for continued and repeated litigation regarding alleged defects in this medical device.

120. Plaintiff therefore seeks a declaration that the Sorin 3T System is defective and that Defendants must expeditiously notify the Class of such defects.

PUNITIVE DAMAGES

121. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

122. Defendants' acts, omissions, and violations as set forth herein constitute intentional, fraudulent, malicious, and/or reckless conduct. Accordingly, Plaintiff and the Class is entitled to an award of punitive damages.

PRAYER FOR RELIEF

Plaintiff, on behalf of himself and all others similarly situated, requests the Court to enter judgment against Defendants as follows:

A. An order certifying the proposed Class, designating Plaintiff as the named representative of the Class, and designating the undersigned as Class Counsel;

B. An award to Plaintiff and the Class of actual damages, punitive damage, costs, and disbursements in this action, including reasonable attorneys' fees, as permitted by law;

C. A declaration that Defendants are financially responsible for implementing and maintaining a fund for the medical monitoring of Plaintiff and Class Members;

D. A declaration that the Sorin 3T System is defective and unsafe for its intended use;

E. An award of pre-judgment and post-judgment interest, as provided by law;

F. Leave to amend this Complaint to conform to the evidence produced at trial; and

G. Such other relief as may be appropriate under the circumstances.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury on all issues so triable.

Dated: January 23, 2017

Respectfully submitted,

MCGOWAN, HOOD & FELDER, LLC

/s/ James L. Ward, Jr.

S. Randall Hood
Fed. ID No. 6103
1539 Health Care Drive
Rock Hill, SC 29732
Phone: 803-327-7800
rhood@mcgowanhood.com

James L. Ward, Jr.
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1501 North Fant Street
Anderson, SC 29621
Phone: 864-225-6228
swelch@mcgowanhood.com

EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

Sorin Group Deutschland GmbH
c/o Ms. Rosina Robinson
Principal Consultant, Regulatory Services
49 Plain Street
North Attleboro, MA 02760

Re: K052601
Stockert Heater-Cooler System 3T
Regulation Number: 21 CFR 870.4250
Regulation Name: Cardiopulmonary Bypass Temperature Controller
Regulatory Class: Class II
Product Code: DWC
Dated: May 15, 2006
Received: May 16, 2006

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Mahney

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K052601

Device Name: Stöckert Heater-Cooler System 3T

Indications for Use:

The Stöckert Heater-Cooler System 3T is used with a Stöckert S3 heart-lung machine and/or any other heart lung machine featuring a separate temperature control for extracorporeal perfusion of durations of up to 6 hours.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052601

JUN - 6 2006

K052601

Traditional 510(k) Premarket Notification
510(k) Summary
Sorin Group Deutschland GmbH, Stöckert Heater-Cooler System 3T

1. SUBMITTER/HOLDER

Sorin Group Deutschland GmbH
Lindberghstrasse 25
80939 Munich
Germany

Contact: Helmut Höfl, Director, Quality Assurance and Regulatory Affairs
Telephone: 011 49 89 323 010

Date Prepared: September 19, 2005

2. DEVICE NAME

Proprietary Name: Stöckert Heater-Cooler System 3T
Common/Usual Name: Heater-Cooler
Classification Name: Cardiopulmonary bypass temperature controller

3. PREDICATE DEVICE

- Cincinnati Subzero Hemotherm (CSZ Hemotherm) (K811742)
- Alpha Omega, Inc. Dual^2 Cooler-Heater (K001520)
- Jostra AB Heater-Cooler Unit 30 (K031544)

4. DEVICE DESCRIPTION

The Sorin Group Deutschland GmbH Stöckert Heater-Cooler System 3T consists of standard and optional components. The standard components comprise the heater-cooler base unit, water connectors, CAN-connecting cable for the S3 System, potential equalization cable, and Operating Instructions. Patient blankets used with the System are already legally marketed in the United States.

5. INTENDED USE

The Stöckert Heater-Cooler System 3T is intended to provide temperature-controlled water to heat exchanger devices (cardiopulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient during cardiopulmonary bypass procedures lasting six (6) hours or less.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Sorin Group Deutschland GmbH bases the claim of substantial equivalence of the Stöckert Heater-Cooler System 3T to the cited predicate devices based on equivalence in intended use, fundamental technological and operational characteristics. Testing submitted in this premarket notification demonstrates that the Stöckert Heater-Cooler System 3T complies with specifications, meets user requirements, and the differences between the proposed device and cited predicate devices do not raise new issues of safety or effectiveness.

EXHIBIT B

GREENVILLE HEALTH SYSTEM

Information Services Center

525 Grove Road
Greenville, SC 29605
ghs.org

July 18, 2014

[redacted]

CERTIFIED AND REGULAR MAIL

To the family of [redacted],

This is in follow up to previous communication with you about the ongoing investigation into the atypical mycobacterium infection outbreak at Greenville Memorial Hospital. In follow up to conversations with [redacted] physician about her diagnosis, culture results, and treatment plan, a representative of the hospital spoke with you to let you know that other patients also have developed an infection with this mycobacterium. At that time, we committed to providing further information to you about the situation as the investigation progressed.

We are now able to provide more details to you. Attached is a written update on that investigation including information such as how and when we became aware of the potential outbreak, what we know about the source of the infection, and what we have done to eliminate further risk to patients.

I hope that this information will provide the additional information you seek. I am truly sorry for your loss. I understand this must be a very difficult time for you. Please be assured that our goal is to provide quality care to every patient who allows us the privilege of caring for them. Although this is not how we would have preferred for your loved one – and we know that you would not have preferred this either, we are confident that it can result in improvements within GHS, and in other healthcare facilities across the U.S.

Just as GHS elected a transparent approach in communicating to you, other patients, and to the public that we are investigating this infection outbreak, we anticipate continuing that transparency. Should you have further questions about the infection investigation, please contact one of our Quality Management staff at (864) 455-7125.

Sincerely,

Robert L. Mobley, M.D.
Medical Director of Quality

Attachments: Update on Infection Investigation, EPA Factsheet

GREENVILLE HEALTH SYSTEM

Information Services Center

525 Grove Road
Greenville, SC 29605
ghs.org

Update on Infection Outbreak Investigation

Background

In late May 2014, an outbreak of an unusual bacterial surgical site infection was suspected at Greenville Memorial Hospital. This is the first time GHS has experienced an outbreak of surgical site infections involving mycobacterium. Mycobacterium abscessus is an environmental contaminant and can be found in water and dust. The environmental bacteria are considered widespread and part of the natural flora of potable water in the U.S. EPA regulations do not require that it be eradicated because the organism is not thought to be harmful to the general public under normal circumstances, said DHEC. There are no national standards of care regarding whether hospitals should screen for this bacterium or how they should treat incoming water.

It has been described as a cause of healthcare-associated infections. The bacterium is harmless in most circumstances but can result in infections if it comes into contact with surgical sites, especially in immuno-compromised individuals. Exposure pathways of potential concern also include ingestion, inhalation and entry of organisms through abraded skin, according to the Environmental Protection Agency.

Investigation

Because of the organism's long incubation period of an average of 79 days in the GHS patients, patients did not typically show signs of infection until as long as several months after their surgeries. The first-recognized patient tested positive in March 2014. Because of the strong surveillance system, we were able to identify the potential problem and take immediate and appropriate action. In May, when several patients developed similar infections with this same mycobacterium, our hospital epidemiologist identified this as a potential infection outbreak. GHS then began an aggressive sequential elimination of potential sources based on epidemiologic evidence. Water studies showed that some water samples inside Greenville Memorial Hospital tested positive for the bacterium.

Preliminary information focused the investigation on ice from a filtered-water ice machine used in the Operating Room during cardiac surgery. During cardiac surgery, cooling techniques are used to stop the heart without damaging the heart tissue. The equipment used for that cooling of the blood and heart uses ice. The ice never directly touches the patient. The ice machine was removed from use on May 21 as a precaution while the investigation continued. Subsequently, ice required for those surgeries was made using sterile water.

As an additional measure, equipment used for cardiopulmonary perfusion was removed from use on June 6 as part of the expanding investigation. That machine used a closed system in which cooled or heated water encased in tubes is run in close proximity to patient blood (also encased in tubes) as part of a heating/cooling procedure used in cardiac surgeries.

At that point, GHS also reached out to the S.C. Department of Health and Environmental Control (DHEC) and Centers for Disease Control and Prevention (CDC), as well as other authorities in atypical mycobacterium for additional expertise with the investigation.

Current Status

As the investigation progressed, we instituted numerous measures focused on reducing or eliminating the levels of mycobacterium within our facilities. Many of these processes were already in place but GHS is continuing or strengthening them. The control measures include:

1. Flushing scrub sinks in the OR for at least 10 minutes in the morning before first use.
2. Installing point-of-use bacteriologic filters in the operating room, including scrub sinks. The filters are able to screen the extremely small bacterium, which is only .2 microns in size and one of the smallest bacteria now known; in comparison, a single human red blood cell is about 5 microns across.
3. Shortening the disinfectant cycle on the machine which actually utilized the ice. GHS has now moved to a weekly disinfectant cycle on the machine, rather than the two week cycle recommended by the manufacturer. This cleaning schedule issue was reported to the U.S. Food and Drug Administration for investigation
4. Inspecting internal water systems to assess for unused plumbing branches and ensuring water flow is constant through the pipes, which would help discourage the organism. GHS engineers have completed this work within the operating room area.
5. Temporarily closing an operating suite associated with the cardiac cases as a precaution. That operating suite reopened July 16, after cultures of the environment were negative.
6. Instituting ultra-violet light disinfection throughout the operating rooms as part of a general disinfection schedule.
7. Ensuring that future installation of plumbing in the facility does not create unused branches in the plumbing system in order to prevent stagnation and microbial contamination of tap water.
8. Using an even stronger disinfecting process that is more effective against this specific organism. All operating rooms were previously disinfected by a standard EPA approved product; however, the product now being used is tuberculocidal.

9. Installing a point of use bacteriologic filter for the ice machine once it is returned to service. Continuing a cleaning disinfection schedule of the ice machine in accordance with manufacturer recommendations.
10. Requesting an independent analysis of the cardiopulmonary perfusion machine. The result of that analysis is that it is unlikely that the equipment allowed tap water to contact patients; nonetheless, the hospital will not return it to use.
11. Devising more stringent internal procedures for cleaning the operating room. For example, covering the OR table -- including preparation for emergency surgery - is done on the day of the surgery and assuring that no operating room bed coverings are present while cleaning is performed.
12. Eliminating use of tap water contact with medical equipment and supplies. GHS does adhere to evidence-based practice, recommendations of regulatory agencies, guidelines from professional societies, as well as manufacturer recommendations for equipment used in the operating room. Prior to this outbreak, and depending upon information from the above sources, the equipment and its purpose, non-sterile water may have come in contact with equipment in the OR when use of sterile water was not required. However, DHEC has advised GHS that exposure to *M. abscessus* may best be avoided by preventing any possible tap water contact with medical equipment and supplies.
13. Continuing to ensure that medications and flushes given during surgery are stored in areas that do not have a water source and, when utilized in the OR, preparation and handling should be done away from any source of tap water or ice.
14. Continuing to emphasize meticulous adherence to infection prevention methods by staff in the operating rooms for the prevention of surgical site infections.

GHS plans to continue working with experts including DHEC and CDC on this investigation. Clinical isolates are being submitted to CDC for molecular analysis and comparison of culture results. GHS plans to continue heightened surveillance for further cases for at least 4 months.

Patient / Family Communication

Communication with individual patients about the situation has been an ongoing process. Each time a GHS surgeon suspected a patient of developing an infection, it was communicated to the patient. The surgeon also discussed culture results and treatment. Physicians are prohibited from discussing a patient's condition with other patients due to privacy laws. However, patients were informed of the infection outbreak, once that outbreak was confirmed. We personally reached out to each of the affected patients or families in order to share information regarding the situation, either by face-to-face conversations or phone calls. Each patient / family we met with was given a card with the name and phone number for someone they could call to request additional information. Our staff continue to support and respond to patient needs.

In addition, although the investigation had not yet provided conclusions, it was decided, out of an abundance of caution, that GHS would notify patients who were believed to be at risk for developing this infection, based on the investigation at that time. A letter was written to make these patients aware of the situation and to ask them to notify their surgeon should they develop signs of infection. That letter was sent to close to 200 patients on whom specific cardiopulmonary surgical equipment had been used, via regular and certified mail.

Even though the overwhelming majority of surgical patients treated at Greenville Memorial have not been affected by this rare mycobacterial infection, because of our commitment to transparency we thought it was important to notify the community about the infection out of extreme precaution to ensure their safety and to alert them about possible symptoms.

We regret that any patient within our care could possibly be affected by this situation. Our thoughts are with those involved. Our ongoing priority is continued safe and effective care for the patients who allow us the privilege of caring for them.

EXHIBIT C

PALMETTO HEALTH

STEVEN FOSTER
112 INWAY DR
COLUMBIA, SC 29223-5473

December 16, 2016

Dear Steven,

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are investigating reports that a device used to heat and cool a patient's blood and organs during open heart surgery has been linked to a rare bacterial infection called *Mycobacterium chimaera* (*M. chimaera*), caused by a type of bacteria known as nontuberculous mycobacterium (NTM). New information indicates that this device, manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH), was likely contaminated with the rare bacteria during manufacturing.

For patients who had open heart surgery that used this heater-cooler device, the chance of getting this infection is extremely low. In hospitals where at least one infection has been identified, the CDC estimates the risk to be less than 1 percent. Of the several thousands of patients who have had open heart surgery at Palmetto Health Richland since 2010, we have no documented cases of a patient with this infection.

We are contacting you because you or a member of your family has been identified in our clinical records as a patient who had heart bypass surgery at Palmetto Health. The overall risk of *M. chimaera* infection is very low relative to other complications following cardiac surgery. Palmetto Health continues to meet and exceed all recommendations made by the CDC and the FDA to ensure the highest possible safety of all patients.

The *M. chimaera* infection is very slow growing and difficult to diagnose. It is possible to develop symptoms years after surgery, so it is important to know the symptoms for such an infection. This infection cannot be spread person-to-person. You should discuss any symptoms or questions you may have with your primary care physician.

Symptoms of *M. chimaera* infection include:

- Persistent or unexplained fever
- Night sweats
- Redness, heat or pus around a surgical incision
- Muscle aches
- Unexplained weight loss
- Fatigue

Please be assured that Palmetto Health continues to have the same commitment to excellence and quality for all of our cardiac surgery patients who we have served for more than 35 years. If you and your family have additional questions or concerns about this information, you can visit our website for frequently asked questions at PalmettoHealth.org/HeaterCoolerQA or contact us at 803-907-0350.

Sincerely,

Sangita Dash, MD
Hospital Epidemiologist
Palmetto Health

Eric A. Brown, MD
Physician Executive
Palmetto Health Richland

EXHIBIT D

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

SORIN GROUP DEUTSCHLAND GMBH · Lindberghstr. 25 · D-80939 München

«Name1»
«Name2»
«Name3»
«Address»
«Address»

FIELD SAFETY NOTICE

Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices

Affected Devices:	Sorin Group perfusion system – Heater Cooler 1T and Heater Cooler 3T devices (refer to Attachment 1 for affected catalog and serial numbers)
Date:	03. June 2015
Reference No:	9611109-06/03/15-002-C
Attention:	Hygiene Specialists, Cardiac Surgery Operating Room Responsible, Risk/ Safety Managers, Distributors, Clinicians, Perfusionist and other users of these devices
Reason:	Sorin has become aware that the actual disinfection practices and the water maintenance that some users have been performing are not always conducted according to our Instructions for Use. Without vigilant performance of the disinfection and maintenance procedures per the Instructions for Use, organisms can multiply in a heater cooler device and potentially form biofilm. The biofilm provides an opportunity for bacteria, including Mycobacteria, to colonize within the device. Once colonized, there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination. Although water from the heater cooler device is not intended to contact the patient directly, fluid leakage from the device or aerosolization generated by a contaminated water circuit during device operation may create conditions in which the organisms could potentially contact the patient and subsequently contaminate the surgical site. Sorin Group is providing this notification to: (1) remind you of the importance of following the company's disinfection and maintenance procedures; (2) inform you that there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination; and (3) provide you with updated Instructions for Use regarding disinfection and maintenance procedures.

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

Dear Valued Customer:

The purpose of this letter is to advise you that Sorin Group Deutschland GmbH ("Sorin") is executing a voluntary field safety correction for the Heater Cooler 1T and the Heater Cooler 3T devices ("heater cooler devices"). This field safety notice describes below, immediate action to be taken by you.

- If your heater cooler device has been strictly maintained according to the Instructions for Use, please strictly adhere to the new Instructions for Use provided in **Attachment 1** of this letter.
- If your heater cooler device has **not** been strictly maintained according to the Instructions for Use, please perform the steps included in the *Immediate Customer Action* section of this letter.

Description of Issue

Sorin has become aware of cases of non-tuberculous mycobacteria endocarditis or deep infection following cardiac surgery during which the heater cooler device was used. There is a risk that surgical patients may experience invasive cardiovascular infection, including endocarditis, or other deep-surgical-site infections due to non-tuberculous mycobacteria, such as Mycobacterium chimaera. Because the symptoms may be slow to manifest, it is possible that many months may pass after completion of the surgical procedure before a surgical patient presents with an infection. In some cases, it is possible that infection could lead to death. Sorin's investigation into these cases is ongoing. To date, the investigation has not determined a causal connection between the heater cooler device and these cases. In some instances there has been a suggestion of such a link; however, infection following cardiac surgical procedures can be caused by numerous, other sources.

The heater cooler device which is provided non-sterile may develop highly contaminated water due to the failure to follow the Instructions for Use for water maintenance and water circuit disinfection. If contaminated water is used in the device **and** the user performs inadequate maintenance and/or fails to strictly adhere to the user instructions for cleaning of the heater cooler device, the device could become a source for contaminating the surgical environment. This condition can occur where there has been a build-up of biofilm within the water circuit of the device. Although water from the heater cooler device is not intended to contact the patient directly, fluid leakage from the device or aerosolization generated by a contaminated water circuit during device operation may create conditions in which the organisms could potentially contact the patient and subsequently contaminate the surgical site.

Contamination of heater cooler units with other waterborne pathogens, like *Mycobacterium abscessus* and non-fermenting gram-negative bacteria, has also been detected in the water of certain heater cooler units. However, no cases of patient infection have been determined to be caused by heater cooler devices. Further, Sorin's investigations into the potential association of heater cooler units with infections by *Mycobacterium chimaera* and other pathogens are ongoing.

If there is a need for further communication based on the investigation results, we will provide you the information.

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www.sorin.com

Geschäftsführer:
Alexander H. J. Neumann
Giulio Cordano

Amtsgericht München
HRB 100852
USt-IdNr. (VAT) DE 129304291
Steuer-Nummer: 143/181/70429

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

Immediate Customer Action

- ✓ Sorin reminds its customers using heater cooler devices about the importance of adhering to correct maintenance of the device at all times and, in particular, to assure that the cleanliness of the water is maintained. **Attachment 1** of this notification includes the new Instructions for Use for the cleaning and disinfection of the Sorin heater cooler devices. Please discard the existing IFU and follow this new IFU which includes updated cleaning and disinfection instructions.
    - o Assure that your team understands Mycobacteria and the potential contamination risks for cardiac surgical procedures, for example, that Mycobacterium is widely distributed in the ecosystem including chlorinated drinking water from the tap, it is inherently resistant to chemical disinfectants and antibiotics, and under the right conditions, it has a propensity to form biofilm and it can also be aerosolized.

- ✓ Healthcare providers involved in the care of patients who have undergone open heart surgery should be vigilant for cases of endocarditis or other cardiovascular infection of unidentified origin with specific testing for slow-growing non-tuberculous Mycobacteria such as *Mycobacterium chimaera* performed as indicated.

- ✓ Verify that this letter has reached your local team and that the recommended monitoring has been considered for your cardiac surgery operating rooms and area. This includes the monitoring of the area water not only for typical microorganisms, but also for slow growing non-tuberculosis Mycobacteria that requires special monitoring practices.

Actions to be taken by the user on the device

- ✓ Review your inventory and identify any heater cooler devices per the attached list, **Attachment 2.**

- ✓ For each unit, determine if the device has been maintained according to the Instructions for Use. If yes, strictly adhere to the new Instructions for Use provided in **Attachment 1** of this notification.

  Note: It is recommended to implement a microbiological monitoring of the water quality (by heterotrophic plate count (HPC) measurement), including monitoring for non-tuberculous Mycobacteria on a monthly basis (Coliform bacteria, P. aeruginosa and non-tuberculous mycobacteria should not be detectable in 100ml). The water in the device should meet microbiological drinking-water quality according to national drinking-water standards.

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SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

✓ If the device has not been maintained according to the Instructions for Use, follow instructions in the table below:
Note: Please consult your Infection Control Manager for executing the following steps.

Step 1 / Submission of Test Sample
✓ Take two 100ml or greater water samples from one of the drain valves at the back of the device **prior to** the disinfection step: (1) for heterotrophic plate count measurement; and (2) for non-tuberculous mycobacteria analysis.
✓ Submit samples (1 & 2) to a microbiological lab for heterotrophic plate count measurement of the water and to determine if non-tuberculous mycobacteria are detectable.
✓ Perform disinfection of the water circuit of the heater cooler device(s) according to the new instructions for use provided in **Attachment 1** of this notification.
✓ Replace any accessories and products that are used in conjunction with the heater cooler device which may be potentially contaminated (e.g. tubing and connectors, graduated beaker, warming blanket) by new or re-processed parts.
✓ While awaiting test results from the microbiological lab, operate the heater cooler device outside of the operating room, if structurally possible, and proceed to **Step 2.** Note: For technical support regarding the installation outside the OR (max. distance, routing) please contact your local service representative.
✓ If it is not possible to move the heater cooler device outside the operating room, take the device out of service or proceed to **Step 3**.
Step 2 / Interim Process (If heater cooler device can be operated outside the operating room)
✓ Perform the water maintenance and disinfection of the water circuit of the device(s) according to the new instructions for use provided in **Attachment 1** of this notification.
✓ Implement a bi-weekly microbiological monitoring of the water quality (by heterotrophic plate count (HPC) measurement), including monitoring for non-tuberculous mycobacteria. The samples shall be taken prior disinfection.
✓ When you receive the results from the lab go to **Step 4**

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SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

Step 3 / Heater Cooler operated in operating room
✓ Place the heater cooler in a way that the flow conditions of the surgical side are not disturbed by the heater cooler device fans. o Maintain maximum distance from surgical field; o Position heater cooler such that the fan exhausts of the device are directed away from the surgical field; o Position heater cooler fan exhausts close to the suction exhaust (outtake) of the operating room. ✓ The water in the tank must be changed **every day**. ✓ In order to prevent microbial growth and to avoid biofilm build-up, add medical grade 3% hydrogen peroxide solution to the tank contents (follow instructions provided in the new IFU, which direct 150 ml for the heater cooler 3T or 50 ml for the heater cooler 1T). ✓ Perform a **weekly** disinfection as described in the new IFU to kill the waterborne pathogens such as non-tuberculous mycobacteria. ✓ Implement a bi-weekly microbiological monitoring of the water quality (by heterotrophic plate count (HPC) measurement), including monitoring for non-tuberculous mycobacteria. The samples shall be taken prior to disinfection. ✓ Take microbiological air samples for non-tuberculous mycobacteria in the operating room when the heater cooler is running on a bi-weekly basis. ✓ When you receive the results from the lab go to **Step 4**
Step 4 / Review of Lab Analysis and Action
✓ If the microbial counts are within the specified limits (meet microbiological drinking-water quality and Coliform bacteria, P. aeruginosa and non-tuberculous mycobacteria are not detected in 100ml), the device can be placed back into the operating room. Continue to use and maintain the device according to the new IFU, **Attachment 1** ✓ Implement a microbiological monitoring of the water quality, including monitoring for non-tuberculous Mycobacteria on a monthly basis. ✓ If you find microbial counts in the water are greater than the limits specified above, contact your infection control manager to determine appropriate actions and immediately contact your service representative for support. ✓ If non-tuberculous mycobacteria are found in the air of the operating room, when the heater cooler is operated, remove the heater cooler from service and immediately contact your service representative for support. o For emergency surgeries please consult your infection control manager to determine appropriate actions.

For technical support please contact your local service representative.

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Please complete and return the attached Confirmation Form (see **Attachment 3**) by fax to «Number» or by email to «E-mail Address».

Transmission of this Field Safety Notice

Please assure within your organization that this notice is communicated to all personnel who need to be aware of this Field Safety Notice. In case you have transferred products to a third party please communicate this information to them and also inform the below mentioned contact person.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person

For questions regarding this Field Safety Notice, please contact Christian Peis, Director QA, Sorin Group Deutschland GmbH at +49 89 323 01 152, via fax at +49 89 323 01 333 or via e-mail at SGD.fsca@sorin.com

A copy of this Field Safety Notice has been provided to the appropriate Regulatory Agencies who are aware of these actions.

Thank you for your cooperation in this matter. Sorin Group is committed to provide quality products and service to its customers and we apologize for any inconvenience this situation may have caused.

Sincerely,

i.V. Christian Peis
Director Quality Assurance

Enclosures:

Attachment 1: New Instructions for Use

Attachment 2: Affected Product List

Attachment 3: Customer Response Form

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SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

Attachment 2
Affected Product List

FIELD SAFETY NOTICE
Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices
Reference # 9611109-06/03/15-002-C

Product Code	Product description	Affected Serial Number range
16-02-50	Heater-cooler 1T, 230V	16S00808 - 16S02268
16-02-80	Heater-cooler 3T, 230V	16S10027 - 16S15641
16-02-81	Heater-cooler 3T, 240V	16S10743 - 16S11708
16-02-82	Heater-cooler 3T, 208V	16S10772 - 16S15523
16-02-83	Heater-cooler 3T, 127V	16S11455 - 16S15190
16-02-85	Heater-cooler 3T, 120V	16S10958 - 16S15634
16-02-95	Heater-cooler 3T, 200V	16S12004 - 16S15385

Please refer to Attachment 3 for affected Systems at your site.

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SORIN GROUP
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Attachment 3 -
Customer Response Form

FIELD SAFETY NOTICE

Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices
Reference # 9611109-06/03/15-002-C

According to our records you have the following affected products:

<Fill in the customer related codes and serial numbers only- Use Attachment 4_Product trace list (Excel File)>

Product Code	Product description	Affected Serial Number

Please correct any inaccurate information above.

Please return this completed form to:

Sorin Site/ Distributor Name: <<Print Your Company name here>>
Country: <<Print Your Country here>>
Contact Name: <<Print Your Contact Name here>>
E-mail: <<Print Your E-mail address here>>
Fax No.: <<Print Your Fax No. here>>
Phone Number: <<Print Your Phone No. here>>

Section 1 - Please Complete:

1. We HAVE reviewed and understand the attached Field Safety Notice ☐ yes ☐ no
2. We DO NOT understand the attached Field Safety Notice and request more information ☐ yes ☐ no
3. WE HAVE discarded the old instruction for use ☐ yes ☐ no

Please contact us:

Christian Peis, Director QA, Sorin Group Deutschland GmbH at +49 89 323 01 152, via fax at +49 89 323 01 333 or via e-mail at SGD.fsca@sorin.com

Customer Name: <<Print Your Company name here>>
Country: <<Print Your Country here>>
Contact Name: <<Print Your Contact Name here>>
E-mail: <<Print Your E-mail address here>>
Fax No.: <<Print Your Fax No. here>>
Phone Number: <<Print Your Phone No. here>>
Submitted by .....
Signature .....
Date ...../...../.....

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EXHIBIT E

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

SORIN GROUP DEUTSCHLAND GMBH · Lindberghstr. 25 · D-80939 München

August 6, 2015

Customer Name
Address
City, State Zip

Subject: Update to the Field Safety Notice for Heater-Cooler System 3T

Dear Valued Customer:

You recently received a Field Safety Notice from Sorin Group regarding the Heater-Cooler System 3T (Reference # 9611109-06/03/15-002-C, dated June 15, 2015).

The purpose of this Field Safety Notice was to:

- Remind you of the importance of following disinfection and maintenance procedures.
- Inform you that if your Heater-Cooler 3T is not properly maintained and it becomes contaminated, there is a possibility that bacteria can be aerosolized when the device is operated serving as a potential source for contamination.
- Provide you with updated instructions for use regarding disinfection and maintenance procedures.

This letter is to inform you that the Heater-Cooler System 3T Operating Instructions provided with the Field Safety Notice dated June 15, 2015 were intended for distribution to English speaking countries in the European Union (EU) rather than for the United States.

Although the EU and USA cleaning and disinfection procedures are equivalent, the EU procedure includes additional chemicals only available in other countries. Additionally, the USA Operating Instructions include information specific to the U.S. such as English units of measure and an Indications for Use statement.

The USA Heater-Cooler System 3T Operating Instructions are attached to this letter.

For your convenience, the USA Heater-Cooler System 3T Operating Instructions are available on the Sorin Group website at www.sorin.com/3t . They can be viewed, saved or printed as you prefer.

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Customer Actions:

- Please discard all existing Heater-Cooler System 3T Operating Instructions and replace them with the attached USA Heater-Cooler System 3T Operating Instructions.
  Note: The current USA Heater-Cooler System 3T Operating Instructions are CP_IFU_16-XX-XX_USA_014. This identification number is printed at the bottom of each page.
- Follow the actions detailed in the Heater-Cooler System 3T Field Safety Notice dated June 15, 2015.
- Please complete and return the attached Customer Response Form by fax to 303-467-6502 or by email to USFSN@sorin.com.

Contact Information:

Please contact your Sorin Group account representative if you have any questions. If further assistance is required, please contact:

Technical Services hotline at 1-800-221-7943, extension 6355

For your reference, we have also created a list of Frequently Asked Questions, Quick Start Instructions and a 3T Disinfection Video on our website at www.sorin.com/3t .

Sorin Group is committed to providing quality products and services. Thank you for your cooperation in this matter. This information will also be provided to the FDA.

Sincerely,

Christian Peis
Director Quality Assurance

Attachment 1: Affected Products List

Attachment 2: Customer Response Form

Attachment 3: USA Heater-Cooler System 3T Operating Instructions

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SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

ATTACHMENT 1

Affected Product List

UPDATE TO THE FIELD SAFETY NOTICE
Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices
Reference # 9611109-06/03/15-002-C

Product Code	Product description	Affected Serial Number range
16-02-80	Heater-cooler 3T, 230V	16S10027 - 16S15641
16-02-81	Heater-cooler 3T, 240V	16S10743 - 16S11708
16-02-82	Heater-cooler 3T, 208V	16S10772 - 16S15523
16-02-83	Heater-cooler 3T, 127V	16S11455 - 16S15190
16-02-85	Heater-cooler 3T, 120V	16S10958 - 16S15634
16-02-95	Heater-cooler 3T, 200V	16S12004 - 16S15385

Please note, all Sorin Heater-Cooler System 3T Devices are affected. Refer to the Customer Response Form for your affected products.

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SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

ATTACHMENT 2

Customer Response Form

UPDATE TO THE FIELD SAFETY NOTICE
Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices
Reference # 9611109-06/03/15-002-C
Including USA Heater-Cooler 3T System Operating Instructions

According to our records you have the following affected products:

Product Code	Product description	Affected Serial Number

Please correct any inaccurate information above.

Please return this completed form: By fax to 303-467-6502 or by email to USFSN@sorin.com.

Section 1 - Please Complete this section:

We HAVE reviewed and understand this Field Safety Notice ☐ Yes ☐ No

WE HAVE implemented the proper Operating Instructions ☐ Yes ☐ No

Customer Name: _____
Contact Name: _____
E-mail: _____
Fax No.: _____
Phone Number: _____

Submitted by .....

Signature ..... Date ...../...../.....

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SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

ATTACHMENT 3

USA Heater-Cooler System 3T Operating Instructions

UPDATE TO THE FIELD SAFETY NOTICE

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EXHIBIT F

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Sorin Group Deutschland GmbH 12/29/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 66
Silver Spring, MD 20993

DEC 29, 2015

WARNING LETTER

VIA UNITED PARCEL SERVICE

André-Michel Ballester
Chief Executive Officer
LivaNova (formerly Sorin Group S.p.A.)
Via Benigono Crespi, 17
Milano, 20159
Italy

Dear Mr. Ballester:

The United States Food and Drug Administration (FDA) conducted the following inspections at your facilities:

- Sorin Group Deutschland GmbH, Lindberghstrasse 25, Munchen, 80939, Germany, (Munchen Facility), dated August 24, 2015, through August 27, 2015; and
- Sorin Group USA, Inc., 14401 W. 65th Way, Arvada, Colorado 80004, U.S.A., (Arvada Facility), dated August 24, 2015, through September 1, 2015.

During the inspection at your Munchen facility, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures Stockert Heater Cooler 3T thermal regulator devices. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body.

These inspections revealed that your firm's devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

We received a response from Mr. Thierry Dupoux, Vice President, Sorin Group Cardiopulmonary BU, Sorin Group Deutschland GmbH, dated September 15, 2015, concerning our investigator's observations noted on the Form FDA 483s (FDA 483), List of Inspectional Observations, which was issued to your firm's Munchen, Germany facility. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i) [Munchen Facility]. For example:

a. Your firm created Design Change Order #8115, dated December 11, 2012, as part of the corrective actions to the FDA Warning Letter dated August 2, 2011, to the Munchen Facility, to address deficiencies in the design change procedures. The change order documents the decisions to change the design input for water quality to add new cleanliness criteria, test the cleaning instructions for use (IFU) to the new input, update the cleaning instructions for use, and validate the new IFU. However:

i. The changed design input is incomplete in that there is no information on how maintaining a cleanliness standard for drinking water applies to the requirement that "biofilm should not grow in the 3T devices". Additionally, there is no information on a water quality standard ensures that the device does not cause waterborne infection; and,

ii. The design validation for the change to the cleaning IFU is inadequate. In the IFU, end users are responsible for conducting the cleaning and disinfection procedure on devices at user facilities. There is no documentation that your firm tested the updated IFU under actual or simulated use conditions to ensure the usability of the cleaning IFU. Your firm has received complaints of patient deaths due to infection from non-tuberculosis mycobacteria (NTM), specifically *mycobacteria chimaera,* since January 2014, where the cause of the infection appeared to be 3T devices colonized with the mycobacteria. Your firm investigated the complaints and determined that the user facilities had not been following the cleaning IFUs, potentially contributing to patient infections.

b. Your firm issued Design Change Orders 9416, 9416-01, 9711, and 9690, corresponding to CAPA 2015-03, and submitted a recall in June, 2015 (#Z-2076/2081-2015), to update the cleaning and disinfection IFU after receiving complaints of patient deaths due to infections caused by the 3T device. As part of this design change, your firm contracted a laboratory to conduct a test on the cleaning procedure in the updated IFU. The resulting test report, dated April 7, 2015, describes the test protocol and results. However, your firm's test report does not demonstrate an adequate verification or validation of the new cleaning IFU because: (reduction) for bacteria, as required by your test procedure. In addition the acceptance criteria do not appear to correspond to the design inputs of drinking water quality, controlling biofilm, or that the device does not cause waterborne infection;

i. The acceptance criteria for the test do not demonstrate that the updated cleaning and disinfection instructions produce a **(b)(4)** level (reduction) for bacteria, as required by your test procedure. In addition the acceptance criteria do not appear to correspond to the design inputs of drinking water quality, controlling biofilm, or that the device does not cause waterborne infection;

ii. Puristeril is not available in the United States, and therefore your firm recommends using Clorox as a substitute in the IFUs. However, the test report does not demonstrate the amounts of Clorox described in the IFU are equivalent to Puristeril;

iii. Two of the challenge bacteria, **(b)(4)** and **(b)(4),** used in the test procedure were not used at a high enough concentration to demonstrate the **(b)(4)** level acceptance criteria;

iv. The exact disinfectant dilution is not clear, because the exact water amounts used were not measured. Water levels were determined by **(b)(4).** No validation for the accuracy of these **(b)(4)** for detecting water levels was documented in the test report;

v. There is no description for how the sampling locations, sampling methods, and machine conditions used represent worst case condition for finding bacteria;

vi. There is no statistical rationale documented in the test report for using testing **(b)(4),** to demonstrate that the cleaning instructions for use will consistently maintain water quality requirements inside 3T devices in the field or clinical setting; and,

vii. There is no documentation that your firm tested the updated IFUs for usability by the end user. Specifically, those responsible for conducting the cleaning and disinfection procedure on devices at user facility.

Your firm's response did not address this deficiency. We note that this is a repeat from a nonconformance noted in the Warning Letter issued to the Munchen facility on August 2, 2011.

2. Failure to validate a process, with a high degree of assurance and approved according to established procedures, a process where results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a) [Munchen facility]. For example, your firm designed and implemented a new cleaning, drying, and disinfection process using (b)(4) at the contract manufacturer, (b)(4), as part of a corrective action. However, the new process was not adequately validated or verified prior to implementation on production units or monitored after implementation. Specifically:

a. Your firm contracted an "efficacy test" at a testing firm, (b)(4), on November 17, 2014, to conduct an in-house validation of the use of the (b)(4) disinfection and drying process to eliminate a mycobacterium test strain from 3T devices to validate the new process. However, the efficacy test was not an adequate verification or validation of the disinfection and drying process because:

i. The efficacy test report documented testing to (b)(4) mixture; however, the disinfection and drying process (b)(4). There was no documentation of justification for using a different concentration, and therefore the test does not accurately reflect the (b)(4) disinfection procedure;

ii. No controls were used in the efficacy test;

iii. Your firm did not provide documentation to describe if a (b)(4) was used (b)(4); and

iv. Your firm did not provide documentation for how the bacteria were (b)(4).

b. Your firm conducted further monitoring of manufactured devices after the (b)(4) disinfection and drying process was implemented. However, the monitoring was inadequate because the following required information for a cleaning and disinfection monitoring report was not documented:

i. The data for recovery efficiency of bacteria from the 3T devices;

ii. The data for complete bioburden: aerobic bacteria, anaerobic bacteria, spores, fungi, and yeast in the devices prior to disinfection. Only aerobic mesophilic bacteria are noted;

iii. The data for bacteriostasis or fungistasis;

iv. The concentration of (b)(4) used in sampling;

v. The time of exposure to the (b)(4); and

vi. Whether (b)(4) was performed after (b)(4).

c. Your firm's disinfection and drying procedure and validation protocol, "(b)(4) cleaning, disinfection, and drying process designed and implemented by your Munchen facility at the contract manufacturer (b)(4). However, the procedure was not adequately validated to ensure that the process completely dries the device.

For example:

i. The protocol states that the transparent pump tubing (b)(4) The protocol did not indicate whether any (b)(4) after drying was acceptable; and

ii. The validation did not include key technical parameters required for validation of a disinfection process. For example:

a. The amount of **(b)(4)** at time 0 (start of experiment);

b. Data to provide a rationale for choosing **(b)(4)** dry the tanks and tubing;

c. Quantification of the term "visually dry" and how to measure dryness by a validated method;

d. Documentation of the **(b)(4)**; and

e. Documentation of environmental conditions for temperature and humidity during the **(b)(4)** device prior to sampling.

We reviewed your firm's response and conclude that it is not adequate. Your firm did not evaluate the potential impact of these violations on distributed devices, and take steps to mitigate the risks as needed.

Our inspection also revealed that your firm's devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting (MDR), but are not limited to, the following:

3. Failure to adequately develop, implement, and maintain written MDR procedures, as required by 21 CFR 803.17 (Arvada facility). For example:

Your firm's MDR procedure, "Standard Operating Procedure for Medical Device Reporting", **(b)(4)**, Rev. AA, updated on October 15, 2012, has the following deficiencies:

a. The procedure does not establish internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements. For example, the procedure omits definition of the term "reasonably suggests," found in 803.20(c)(1). The exclusion of this definition for this term from the procedure may lead your firm to make an incorrect reportability decision when evaluating a complaint that may meet the criteria for reporting under 21 CFR 803.50(a);

b. The procedure does not establish internal systems that provide for timely transmission of complete medical device reports. Specifically, the procedure does not address how your firm will submit all information reasonably known to it for each event;

c. The procedure does not describe how it will address documentation and record-keeping requirements, including:

i. Documentation of adverse event related information maintained as MDR event files'

ii. Information that was evaluated to determine if an event was reportable;

iii. Documentation of the deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable; and

iv. Systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

In addition, we have noticed deficiencies in your firm's (Munchen facility) MDR procedure, "**(b)(4)**, Rev. 003. Specifically, the MDR procedure does not have an effective date.

Please note, the MDR procedures at the Munchen and Arvada facilities include references to submitting MDRs to FDA using the following address: FDA, CDRH, Medical Device Reporting, P. O. Box 3002, Rockville, MD 20847-3002. Please note that effective August 14, 2015, MDRs should be submitted electronically and paper submissions will not be accepted, except under special circumstances, directed by FDA. For more information about electronic reporting, please refer to the eMDR website and the eMDR guidance document. **http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm (http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm)**

Our inspection at your Munchen facility also revealed that the Heater Cooler 3T device is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g). The Heater-Cooler System 3T is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution as required by section 510(k) of the Act, 21 U.S.C. § 360(k).

Specifically, your firm distributed the Heater-Cooler System 3T, cleared under K052601, with modified Instructions for Use (Versions 013 and 014) with respect to the operating, maintaining, cleaning and disinfecting of the device. Some of the modifications found in Versions 013 and 014 include: adding more instruction details, changes to the cleaning/disinfecting process (e.g., chemicals used and amounts used), and expansion to the process to include the entire circuit instead of only the tanks. These are significant labeling changes that can affect the safety or effectiveness of the device, and therefore require a new 510(k) in order to be assured that appropriate testing and validation of the cleaning/disinfecting protocols have taken place.

For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency, 21 CFR 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for the device is described on the Internet at:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm. (/MedicalDevices/default.htm)

The FDA will evaluate the information that you submit and decide whether your product may be legally marketed.

Our inspections also revealed that your firm's Heater-Cooler System 3T devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 806 – Medical Devices; Reports of Corrections and Removals. Significant violations include, but are not limited to, the following:

Failure to submit a written report to FDA of any correction or removal of a device initiated to remedy a violation of the act caused by the device which may present a risk to health, as required by 21 CFR 806.10. For example: A change order was initiated on December 20, 2011, related to a change consisting of updating the devices' IFU to indicate a new cleaning and disinfection procedure. Subsequently, the change was implemented in the IFU to indicate the use of a water filter and to add Hydrogen Peroxide to the water used in the devices. A letter was sent to your customers notifying them of the new IFU. The letter stated that the instructions for the device had been updated to assure the user can maintain the cleanliness of the water in the device, and that the 'Updated Instructions for Water Cleanliness' replaced the previous water cleaning instructions for the 3T Heater Cooler. Your firm did not submit a written report to FDA of the correction and removal, as required by 21 CFR 806.

Given the serious nature of the violations of the Act, the Heater Cooler 3T devices, and other devices manufactured by your Munchen facility are subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they appear to be adulterated. As a result, FDA is taking steps to refuse entry of these

devices into the United States, known as "detention without physical examination," until these violations are corrected. In order to remove the devices from detention, your firm should provide a written response to this Warning Letter as described below and correct the violations described in this letter. We will notify you regarding the adequacy of your firm's response and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

Also, U.S. federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected.

Please notify this office, in writing within fifteen business days from the date you receive this letter, of the specific steps your firm has taken to correct the noted violations, including an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Please provide a translation of documentation not in English to facilitate our review.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Inspections Support Branch, White Oak Building 66, Rm 2622, 10903 New Hampshire Ave., Silver Spring, MD 20993.Refer to CMS case #484629 when replying. If you have any questions about the contents of this letter, please contact: Shumaya Ali, Acting Chief, Foreign Enforcement Branch, at feb@fda.hhs.gov (email), or +1 (240) 402-4020 (phone), or +1 (301) 847-8139 (fax).

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely yours,
/S/
CAPT Sean Boyd
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Center for Devices and
Radiological Health

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