IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF LOUISIANA

C.A. No.: _____

Magaly De La Cruz Gonzalez, individually and on behalf of her minor daughter, Genesis De La Cruz, Plaintiffs, -versus- Sorin Group Deutschland GMBH and Sorin Group USA, Inc., d/b/a Liva Nova PLC, Defendants.	**COMPLAINT** **(Jury Trial Requested)**

Plaintiffs, Magaly De La Cruz Gonzalez, individually and on behalf of her minor daughter, Genesis De La Cruz, complaining of the acts of the Defendants above named, would respectfully show unto the Court as follows:

PARTIES TO THIS ACTION

1. Plaintiffs, Magaly De La Cruz Gonzalez, individually and on behalf of her minor daughter, Genesis De La Cruz, are residents and citizens of Lafourche Parish, State of Louisiana. On or about June 27, 2017, Genesis De La Cruz ("Genesis"), underwent a cardiac procedure at Children's Hospital in New Orleans, Louisiana, during which the Sorin Stockert 3T Heater-Cooler System was utilized, exposing her to Nontuberculosis Mycobacteria (NTM).

2. Upon information and belief, Defendant Sorin Group Deutschland GMBH ("Sorin") is a foreign for-profit corporation, with headquarters in Munich, Germany. Sorin designed, manufactured and marketed the Sorin 3T Heater-Cooler System used in

Genesis' surgical procedure at Children's Hospital in New Orleans, Louisiana. The Plaintiffs are under the information and belief that Sorin is the entity responsible for manufacturing the Sorin 3T Heater-Cooler Systems and distributing them to Sorin Group USA for marketing and distribution within the U.S.

3. Upon information and belief, Defendant Sorin Group USA, Inc. ("Sorin USA") is a United States designer, manufacturer, marketer, and distributor of the Sorin 3T Heater-Cooler System, with its principal place of business in Arvada, Colorado.

4. Plaintiffs are under the information and belief that Defendants Sorin and Sorin USA are subsidiaries of LivaNova PLC, a company that serves solely as the "holding company" of Defendants Sorin and Sorin USA. Sorin USA is responsible for the marketing and distribution of the Sorin 3T Heater-Cooler Systems within the U.S.

JURISDICTION AND VENUE

5. This Court has Personal Jurisdiction over this action pursuant to FRCP 4 and pursuant to La. R.S. § 13:3201. The Defendants are non-domiciliaries of the State of Louisiana and contract business within the State of Louisiana; the Defendants have committed tortious acts within the State of Louisiana, causing injury to persons, including the Plaintiffs, within the State of Louisiana, and said Defendants expect or should reasonably expect to have consequences in the State of Louisiana; the Defendants solicit business and engage in persistent courses of conduct and derive substantial revenue from goods used and services rendered in the State of Louisiana; the 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, Sorin Group Stockert Heater-Cooler 3T thermal regulator devices in the State of Louisiana.

6. This Court has Subject Matter Jurisdiction over this action pursuant to 28 U.S.C. § 1332 because complete diversity exists between the parties and the amount in controversy exceeds $75,000.00.

7. Venue is proper in the Eastern District of Louisiana, pursuant to 28 U.S.C. § 1391(a)(2), because a substantial part of the events or omissions giving rise to the causes of action occurred in Louisiana and, pursuant to 28 U.S.C. § 1391(c), because Defendants are subject to Personal Jurisdiction in the Eastern District of Louisiana.

FACTUAL ALLEGATIONS

8. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

9. The Defendants manufacture, market, and sell/distribute thermal regulator devices to be used on patients in the operating room, including the Sorin 3T Heater-Cooler System ("Sorin 3T System"). Prior to June 27, 2017, the Defendants manufactured, introduced, and/or delivered for introduction into interstate commerce, the Sorin 3T System.

10. 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").[1]

11. Before commercial distribution in the United States of the Sorin 3T System, Defendant Sorin 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.[2] Essentially, the 510k process differs from the PMA process in how carefully the FDA examines the safeness 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.

12. 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 (21CFR part 807); Labeling (21CFR part 801); Good Manufacturing Practice Requirements as set forth in

[1] 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 CFR 807.92(a)(3).
[2] Please see the FDA Determination Letter of Approval attached hereto as "Exhibit A".

the Quality Systems Regulation (21CFR part 820); and if applicable, the Electronic Product Radiation Control Provisions (Sections 531-542 of the Act); 21CFR 1000-1050."

13. On or about November 16, 2016, Children's Hospital sent out letters to certain patients that had undergone cardiac procedures wherein the Sorin 3T heart-lung machine was used, to advise the patients and their families of the potential for NTM infections to those undergoing these types of procedures. The letter indicated that the "potential for this infection is incredibly low" and that Children's Hospital would be "following all recommendations from the CDC, FDA, and the manufacturer to minimize any possible risk to patients."[3]

14. Thereafter, a second letter was sent to the Plaintiffs, personally, on August 30, 2017, to inform them that in "mid-August, 2017, several patients who underwent cardiac surgery at Children's Hospital between early June and July, 2017, developed a rare surgical site infection caused by *Mycobacterium abscessus* [(m. abscessus)]." Moreover, the letter indicated that the cause of these infections was believed to be "a piece of equipment used to regulate the temperature of patients while on bypass" and that "all suspected equipment ha[d] been removed from service and replaced."[4]

15. M. abscessus is a part of a group known as "rapidly growing mycobacteria" and is most commonly found in water, soil, and dust. If allowed within the operative field, it poses a significant health risk to surgical patients and patients that are immunodeficient.[5]

[3] Please see Exhibit B attached hereto, which is a copy of the November 16, 2016 letter.
[4] Please see Exhibit C, attached hereto, which is a copy of the August 30, 2017 letter to Plaintiffs.
[5] Centers for Disease control website: http://www.cdc.gov/HAI/organisms/mycobacterium.html

16. M. abscessus can take anywhere from weeks to years before it manifests into a non-tuberculosis mycobacterium infection.

17. Tissue that has been infected with m. abscessus usually presents as "red, warm, tender to the touch, swollen, and/or painful" and infected areas can appear as "boils." Additional signs and symptoms of the infection include "fever, chills, muscles aches, and a general feeling of illness."[6]

18. Diagnosis of m. abscessus can be made from a laboratory analysis of a sample or biopsy of the infected area. In severe cases, the bacterium can be found in the blood and isolated from a blood sample.

19. Targeted cultures, screenings, and proper testing is usually not performed unless the physician has been made aware of this type of mycobacterium exposure. [7]

20. While death is certainly a risk of this type of infection, there are treatments available. Those include draining collections of pus or removing the infected tissue coupled with rigorous administration of a series of appropriate antibiotics for prolonged periods of time. The type and period of treatment can vary greatly from patient to patient.[8]

21. On July 15, 2015, the FDA issued a Class II Recall of the Sorin 3T System due to the "potential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."[9]

[6] Id.
[7] Id.
[8] Id.
[9] Please see the Recall Information from the FDA database, attached hereto as "Exhibit D."

22. The recall instructed all affected customers to follow *new* Instructions for Use, which were outlined in the June 15, 2015 and August 6, 2015 Field Safety Notice Letters[10], issued by i.V. Christian Peis, the Director of Quality Assurance for Sorin.

23. Sorin indicated that it was providing the Field Safety Notice Letter for the following reasons:

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

B. [To] inform [affected users] 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

C. [To] provide [affected users] with updated instructions for use regarding disinfection and maintenance procedures.[11]

24. Upon information and belief, the Defendants knew or should have known that design and/or manufacturing defects in its Sorin 3T System made it susceptible to bacterial colonization, specifically NTM, despite any cleaning and disinfection procedures utilized.

25. 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

[10] Please see the 6/15/15 and 8/6/15 Field Safety Notice Letters, attached hereto as "Exhibit E." These two letters differ in that the Operating Instructions provided in the 6/15/15 letter was intended for distribution to English speaking countries in the European Union (EU), whereas the 8/6/15 letter was intended for distribution in the U.S. Sorin claimed that while "…EU and USA cleaning and disinfection procedures are equivalent, the EU procedures include additional chemicals only available in other countries." Moreover, the U.S. Operating Instructions "…include information specific to the U.S. such as English units of measure and an Indications for Use statement."
[11] Id.

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."[12]

26. The FDA noted several other violations by the Defendants in the Warning Letter, which include, but are not limited to, the following:

A. 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);

B. 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);

C. The devices were misbranded in that Sorin failed or refused to furnish material or information respecting the device that is required by or under § 519 of the Act 21 USC § 360i and 21 CFR Part 803 – Medical Device Reporting;

D. Failure to adequately develop, implement, and maintain written MDR procedures, as required by 21 CFR 803.17;

E. Defendants' Sorin 3T System was misbranded due to its failure to notify the agency of its intent to introduce the device into commercial distribution as required by § 510(k) of the Act, 21 USC §360(k); and

[12] Please see the 12/29/15 Warning Letter, attached hereto as "Exhibit F."

F. Failure to notify the agency of significant labeling changes that affected the safety and effectiveness of the device (i.e., distributing the device with modified instructions for use with respect to the operating, maintaining, cleaning and disinfecting of the device, among other modifications).

27. Contrary to the Defendants' representations and marketing to the FDA, medical community, and to the patients themselves, Defendants' Sorin 3T System has high injury and complication rates, fails to perform as intended, requires patients to undergo additional operations, and has caused severe and sometimes irreversible injuries, conditions, and damages to a significant number of patients, including the Plaintiffs, all of which are violations of Federal and Louisiana State rules and regulations.

28. In violation of Federal and Louisiana State requirements, the Defendants consistently under-reported and withheld information about the propensity of the Sorin 3T System to experience complications and its failure to perform as expected, has misrepresented the efficacy and safety of Defendants' System through various means and media, actively misleading the FDA, the medical community, patients, and the public at large.

29. Defendants knew, and continue to know, that its disclosures to the FDA, the public, and Plaintiffs, were, and are, incomplete and misleading and that the Sorin 3T System was and is causing numerous patients severe injuries and complications, which violates Federal and State requirements. Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, the medical community, health care providers, and patients. As a result,

the Defendants actively and intentionally misled the FDA and the public, including the medical community, healthcare providers, and patients, into believing that the Sorin 3T System was safe and effective, leading to the use of Defendants' System during surgical procedures, such as the one undertaken on Genesis, as more fully described herein.

30. In violation of Federal and State rules and regulations, the Defendants failed to perform and/or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Sorin 3T System.

31. As compared to similar systems, feasible and suitable alternative designs, procedures, and instructions for use have existed at all times relevant.

32. The Defendants' 3T Sorin System was at all times relevant, utilized in a manner foreseeable to the Defendants.

33. The Defendants provided incomplete, insufficient, and misleading instructions, training, and information to hospitals and physicians, which is in direct violation of Federal and State regulations and in violation of regulations required pursuant to the 510K Approval of the Sorin 3T System in order to increase the number of hospitals and physicians utilizing the device, thereby increasing its sales.

34. The Sorin 3T System used during Genesis' surgical procedure was in the same or substantially similar condition as it was when it left the possession of the Defendants, and in the condition directed by and expected by the Defendants.

35. The injuries, conditions, and complications suffered due to the Sorin 3T System include, but are not limited to, excruciating pain, weakness, excessive additional and debilitating medical treatment, suffering, and death. Additional information that may be necessary to further establish Plaintiffs' claims will be gathered throughout the

discovery process of this litigation since Plaintiffs are privy to limited supporting documentation at this time.

36. Despite Defendants' knowledge of the catastrophic injuries, conditions, and complications caused by the Sorin 3T System, in violation of Federal and State requirements, it continued to manufacture, market, provide inadequate instructions for use, and sell the Sorin 3T System, and also failed to adequately warn, label, instruct, and disseminate information with regard to Defendants' Sorin 3T System both prior to and after the marketing and sale of the System.

FACTS SPECIFIC TO THIS CASE

37. On June 27, 2017, the Defendants' Sorin 3T System was used during Genesis' bilateral branch pulmonary arterioplasty procedure, wherein her surgeon used the device to assist in the cooling and re-warming of her blood. Genesis was subsequently discharged from Children's Hospital on or about July 2, 2017. Upon discharge, her surgical incisions were intact and healing well.

38. Thereafter, the Plaintiffs began to notice pain, swelling, and tenderness in the area of Genesis's incision site. On or about August 10, 2017, Plaintiffs relayed these issues to her pediatric cardiologist. Genesis was instructed to return to Children's Hospital for further evaluation of the sternal wound infection by her surgeon.

39. As a result of the sternal wound infection, Genesis was re-admitted to Children's Hospital on or about August 11, 2017. Upon admission, an Irrigation and Debridement procedure was performed and sternal wound cultures were obtained. She was then taken to the CICU.

40. Cultures returned with positive findings of an m. abscessus infection and a rigorous course of antibiotics were instituted, including Zyvox, Zithromax, and Amikacin. Moreover, wound vac was placed on August 13th and a peripheral IV was placed on August 17th. On or about August 29th, a left internal jugular broviac central line catheter was placed due to the need for long-term IV access.

41. Genesis remained at Children's Hospital until her discharge on or about October 10, 2017. She continued to treat with an antibiotic regimen for more than four months until early March 2018.

42. Thereafter, Genesis has continued to follow up with Infectious Disease and Cardiology for therapy and medical management.

43. As a result of the m. abscessus infection, Genesis was forced to undergo numerous additional surgical procedures, medical management, and an extensive course of antibiotic therapy that has caused numerous adverse side effects, including the possibility of future hearing loss.

COUNT I – LPLA CLAIMS FOR DESIGN DEFECTS, MANUFACTURING DEFECTS AND WARNING DEFECTS

44. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

45. The Sorin 3T System is a product within the meaning of Louisiana Products Liability Act ("LPLA"). *See* La. R.S. 9:2800.51 *et seq.* The Sorin 3T System was expected to reach, and did reach, users and/or consumers, including the Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed. At all times material and relevant, the Sorin 3T System was used in a manner intended and/or foreseeable to the Defendants for the purposes of heating and

cooling patient blood during major cardiac procedures and was so used by this Plaintiff for those purposes of which it was marketed, advertised, promoted, and instructed to be used, including cardiac procedures.

46. A patient or consumer utilizing the Sorin 3T System would reasonably expect the device to be free of significant defects. The Sorin 3T System, as designed by the Defendants, colonizes NTM and directly transmits that bacteria to the patient during invasive surgical procedures.

47. The Defendants' intended design and intended manufacturing process for the Sorin 3T System did not include a product contaminated with NTM in the production at Defendants' facilities or through the devices foreseeable and intended use; however, the device did become contaminated with NTM, including the one used during Genesis' procedure, during the manufacturing process and/or through foreseeable and intended use in accordance to the Defendants' instructions, specifically, m. abscessus, and therefore the device deviated in a material way from the Defendants' specifications or performance standards for the Sorin 3T System, at the time it left the Defendants' control, making it defective and unreasonably dangerous in construction and composition.

48. The foreseeable risks of using the Sorin 3T System as designed and instructed significantly outweighs the benefits, and, at the time the Sorin 3T System left Defendants' control, safer, more practical, feasible, and otherwise reasonable alternative designs existed and could have been adopted for the device which would have prevented or substantially reduced the risk of harm (i.e., bacterial colonization and transmission thereof through aerosolization) to the patients, including Genesis, without substantially impairing the usefulness of the device. The risk and gravity of that harm clearly

outweighed the burden on the Defendants of implementing such alternative design. Reasonable alternative designs included, but are not limited to, measures to ensure the vent and consequential airflow did not create a direct path for NTM to travel into the patient's surgical field, measures to allow for easier disinfection, measures to prevent biofilm formation (i.e., disposable liners, etc.), internal features to prevent colonization of bacteria formation, technology aimed at reducing bacterial contamination within the unit, and/or measures to provide some type of protection, barrier and/or enclosure on or around the exhaust vent or even the unit itself.

49. Defendants' failure to use feasible and reasonable alternative designs that would eliminate bacterial colonization (including the colonization of NTM) and aerosolization of that bacteria into the surgical field of patients undergoing cardiac procedures, make the Sorin 3T System unreasonably dangerous and defective and unreasonably unsafe for its intended purpose.

50. Had Plaintiffs or any other reasonable similarly situated person known of the unreasonableness of the Sorin 3T System and its unsafe design as described herein, they would not have utilized the device during the cardiac procedure.

51. Defendants knew or should have known that the Sorin 3T System, as designed, could cause NTM to colonize within the system and cause contamination to patients during invasive cardiac procedures through the device's exhaust vent as early as 2002, and certainly, between the time of sale of the device and the time that it was used during Genesis' procedure. However, the Defendants did not adequately warn patients or users of the risk of NTM colonization within the Sorin 3T System and its propensity to aerosolize through the exhaust vent into the patient's surgical field, nor did

the Defendants adequately instruct users of the Sorin 3T System on the proper cleaning and disinfection procedures to prevent such colonization and aerosolization.

52. The Sorin 3T System utilized during Genesis' surgery was sold without adequate warnings or instructions for use, which rendered the device unreasonably dangerous and defective and it posed a substantial risk of harm to Genesis and any reasonably foreseeable patients.

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

54. The Defendants breached this duty by designing, labeling, manufacturing, assembling, inspecting, testing, marketing, advertising, promoting, distributing, instructing, and selling/distributing the Sorin 3T System in an unreasonably dangerous, defective and unreasonably unsafe condition including, but not limited to, its propensity for the colonization of organisms, including NTM, and the transmission of that bacteria to patients undergoing invasive surgical procedures.

55. The Defendants owed Plaintiffs a duty of reasonable care to discover defects and/or errors in the machine and to inform and/or warn the FDA and Plaintiffs of a defect once it was discovered. The Defendants violated these duties when it failed to do so, which further placed the Plaintiffs at risk for harm and injury.

56. 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 Children's Hospital during Genesis' cardiac procedure was done so in violation of those requirements.

57. The 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 laid out in the FDA approval. The Defendants violated these duties when it failed to comply therewith and distributed a device that deviated from the statutory requirements.

58. As a direct and proximate result of Defendants' violations, the Plaintiffs have suffered severe debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost enjoyment of life, lost income, mental anguish and emotional distress, scarring, and pain and suffering, all of which are continuous in nature.

59. As the manufacturer of the unreasonably dangerous and defective Sorin 3T System, the Defendants are liable to the Plaintiffs for their damages proximately caused by the Sorin 3T System, pursuant to the LPLA, because such damage arose from a reasonably anticipated use of the Sorin 3T System during Genesis' surgery.

COUNT II - BREACH OF EXPRESS WARRANTY UNDER LPLA

60. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

61. The Defendants warranted, both expressly and impliedly, through its

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.

62. The Defendants are aware that health care providers and patients, including Genesis, rely upon the representations made by the Defendants when choosing, selecting, and purchasing its products, including the Sorin 3T System, which was relied upon by these Plaintiffs. Indeed, the express and implied warranties made by the Defendants about the Sorin 3T System induced Children's Hospital to use the Sorin 3T System.

63. As previously discussed and further identified herein, due to the defective and unreasonably dangerous design, labeling, manufacturing, and distribution of the Sorin 3T System, which was in violation of statutory requirements and regulations, the product 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 Genesis, during foreseeable use.

64. The Defendants' violations of Federal and State statutory rules and regulations and the defective and unreasonably dangerous condition of the Sorin 3T System constituted a breach of the Defendants' express and implied warranties, and such breaches were a direct and proximate cause of the incident and damages described herein, and for which Plaintiffs are entitled to compensatory and punitive damages in an amount to be proven at trial.

COUNT III – LUTPA CLAIM

65. The Plaintiffs incorporate by reference, as if fully set forth herein, each

and every allegation in this Complaint.

66. At all times relevant to this action, the Louisiana Unfair Trade Practices and Consumer Protection Law ("LUTPA"), codified at La. R.S. 51:1401 *et seq.*, was in effect. LUTPA provides, in pertinent part, that: "Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are declared unlawful." La. R.S. 51:1405(A).

67. The Defendants have engaged in deceptive acts or practices in violation of the LUTPA, including but not limited to, utilizing deception, fraud, misrepresentation, concealment, omission, and suppression of research from investigations, adverse events reported to the FDA, and clinical trials regarding the safety, efficacy, instructions for use, and the unreasonably dangerous nature of the Sorin 3T System.

68. The Defendants violated the LUTPA by concealing, omitting, and failing to inform the FDA, the Plaintiffs, the medical community, and other purchasers of the failures, adverse reactions, complications, and the insufficiency of the Instructions For Use as it related to the Sorin 3T System.

69. Defendants' deceptive acts and practices occurred during a course of conduct involving trade or commerce.

70. As a direct and proximate cause of the Defendants' violations of Federal requirements and LUTPA, the Plaintiffs have sustained, severe physical and emotional injuries and ascertainable economic loss, which are continuous in nature, for which Plaintiffs are entitled to attorney's fees and compensatory and treble damages in an amount to be proven at trial.

ACTUAL DAMAGES

71. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

72. As a direct and proximate result of the acts, omissions, and violations of the Defendants alleged herein, the Plaintiffs suffered injuries and damages. The injuries and damages for which Plaintiffs seek compensation from the Defendants include, but are not limited to:

a. physical pain and suffering of a past, present and future nature;

b. emotional pain and suffering of a past, present and future nature;

c. permanent impairment and scarring;

d. medical bills and expenses of a past, present and future nature;

e. loss of past and future lost wages and loss of earning capacity;

f. loss of enjoyment of life;

g. pre- and post-judgment interest;

h. statutory and discretionary costs; and

i. any and all such further relief, both general and specific, to which they may be entitled to under the premises.

JURY DEMAND

73. Plaintiff demands a trial by jury on all issues, pursuant to Rule 38 of the Federal Rules of Civil Procedure.

PRAYER FOR RELIEF

74. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

75. **WHEREFORE, PREMISES CONSIDERED,** the Plaintiffs bring this Complaint against the Defendants for personal injuries and pray for a judgment against the Defendants for compensatory damages, in an amount considered fair and reasonable by a jury and for all such further relief, both general and specific, to which Plaintiffs may be entitled under the premises.

Respectfully submitted,

PLOTKIN, VINCENT & JAFFE, L.L.C.

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Pro Hac Vice Motion Forthcoming

Attorneys for the Plaintiffs,
Magaly De La Cruz Gonzalez, individually and on behalf of her minor daughter, Genesis De La Cruz

EXHIBIT

"A"

LOS26601

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.

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,

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

EXHIBIT "B"

CHILDREN'S HOSPITAL

November 16, 2016

Dear Heart Institute Families,

Children's Hospital New Orleans is notifying patients and families who have had open-heart surgery about a potential infection risk. While the risk to our patients is extremely low, we wanted to alert all of our patients.

The Centers for Disease Control & Prevention (CDC) and Food and Drug Administration (FDA) are investigating reports that a common device used to heat and cool the blood during open-heart surgery has been linked to a rare bacterial infection caused by Mycobacterium chimaera, a type of bacteria known as nontuberculous mycobacterium (NTM). The chances of getting this infection from open-heart surgery are extremely low.

As you know, there are inherent risks with any procedure. These heating and cooling devices are essential to the success of open-heart surgeries, and there are no other acceptable devices for us to use at this time. Children's Hospital is following all recommendations from the CDC, FDA and the manufacturer to minimize any possible risk to patients.

We also have conducted and will continue to conduct diligent surveillance for the bacteria. We have evaluated all patients with post-operative infections as far back as 2008 and found zero patients with Mycobacterium chimera.

This infection cannot be spread from person to person. It is very slow growing and difficult to diagnose. The symptoms of infection are nonspecific and thus, could be related to other more common causes of infection.

Again, we want to stress that the potential of this infection is incredibly low. However, if you have any questions or concerns, please contact your cardiologist. You also can find additional information on the CDC website: www.cdc.gov/hai/outbreaks/heater-cooler.html. If you have additional questions, please call (504) 896-2076.

Please know that quality and safety are always a top priority at Children's Hospital. Like you, we only have our patients' best interests at heart.

Sincerely,

John Heaton, MD
Senior Vice President, Chief Medical Officer

Joseph Caspi, MD
Chief Pediatric Cardiac Surgery

200 Henry Clay Avenue
New Orleans, Louisiana 70118
(504) 899-9511
www.chnola.org

EXHIBIT "C"

CHILDREN'S HOSPITAL

August 30, 2017

Dear Ms. Delacruz,

As a follow up to our ongoing conversations, I am writing to let you know that in mid-August 2017, several patients who underwent cardiac surgery at Children's Hospital between early June and July, 2017, developed a rare surgical site infection caused by *Mycobacterium abscessus*. The infections are treatable. Infections caused by *Mycobacterium abscessus* are curable with a combination of antibiotics and surgical care of the incision. Giving antibiotics to patients who are showing no sign of infection is not recommended.

At this point in time, a small minority of patients who have undergone surgery during the period of concern have shown signs or symptoms of problems, but because of the slow onset and unusual nature of this infection we are notifying all patients of our concerns and findings.

Signs of infection of a surgical wound include:

- Swelling of the surgical incision
- Wound drainage
- Redness
- Fever

Unlike common surgical site infections, infections with *Mycobacterium abscessus* may not show all the signs listed above. **Therefore, we are asking that you seek evaluation of the surgical wound by our team at Children's Hospital, or if that is impossible, by your referring cardiologist.**

This is the first time Children's Hospital has experienced a group of surgical site infections caused by this bacteria. *Mycobacterium abscessus* is commonly found in water, soil, and dust. However, this is a highly unusual cause of surgical wound infections; thus, the occurrence of these infections triggered an immediate, thorough investigation.

200 Henry Clay Avenue
New Orleans, Louisiana 70118
(504) 899-9511
www.chnola.org

Because a common element in the affected children was open-heart surgery requiring the use of cardiopulmonary bypass, our investigation focused on the environment and equipment used in the cardiac operating room. We believe a piece of equipment used to regulate the temperature of patients while on bypass is the most likely source of this infection, and all suspected equipment has been removed from service and replaced. Although we have not reached final conclusions, we are reaching out to the families of all patients possibly affected to alert you of the **increased risk of wound infection**, and to provide care and heightened follow up care for your child.

Children's Hospital has a hotline number (504-896-2920) staffed 24 hours a day to field questions or requests for appointments. Every patient receiving this letter has also been contacted by phone, and a letter to bring to your pediatrician or referring cardiologist is included in this mailing. However, it is our strong preference that you have the surgical wound evaluated by the specialists at Children's Hospital.

Upon discovery, hospital leadership took immediate action to address the issue, to investigate and identify the cause, and to proactively inform affected and potentially affected patients' families and all relevant governmental agencies of the situation. We have enlisted the assistance and expertise of the Louisiana Office of Public Health, the Centers for Disease Control, and outside infection control consultants. Our response team has also consulted other hospitals that have dealt with the same issue in the past for guidance and information regarding lessons learned and best practices for treatment. It is our intention that no patient affected by this situation will incur additional clinical cost for resulting treatment or evaluation.

We regret that any of our patients could possibly be affected by this infection. Our thoughts are with those involved, and we apologize for any anxiety caused by this communication. Our ongoing priority is continued safe and effective care for our patients. The safety and health of your child is our first concern, and our team stands ready to answer any questions and provide any necessary treatment.

Sincerely,

John F. Heaton, MD
Senior Vice President
Chief Medical Officer

EXHIBIT "D"

Class 2 Device Recall STOCKERT HEATERCOOLER SYSTEM 3T

See Related Information[22]

Date Posted	July 15, 2015
Recall Status[1]	Open
Recall Number	Z-2076-2015
Recall Event ID	71593[23]
510(K)Number	K052601[24]
Product Classification	Controller, temperature, cardiopulmonary bypass[25] - **Product Code** DWC[26]
Product	Sorin Stockert Heater-Cooler 3T, 230 V Temperature control for extracorporeal perfusion of durations up to 6 hours.
Code Information	Product code 16-02-80 Serial number 16S10027-16S15641
Recalling Firm/ Manufacturer	Sorin Group USA, Inc. 14401 W 65th Way Arvada CO 80004-3503
For Additional Information Contact	Cheri Voorhees 303-467-6306
Manufacturer Reason for Recall	Potential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per Instructions for Use.
FDA Determined Cause [2]	Error in labeling
Action	Sorin Group issued a Field Safety Notice dated June 15, 2015, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to review their inventory and identify any affected devices. For each unit customers were instructed to determine if the device has been maintained according to the Instructions for Use. If yes, customers should strictly adhere to the new Instructions for Use. Customers were also provide with a Response form to confirm they received, read and understood the Field Notice. Customers were instructed to return the completed form to assist in monitoring the effectiveness of the communication. For technical support customers should call 1-800-221-7943, ext 6355. For questions regarding this recall call 303-467-6306.
Quantity in Commerce	2837
Distribution	Worldwide Distribution - US (nationwide) and Internationally to AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SK, AE, AR, AU, AZ, BD, BH, BR, BY, CA, CL, CN, CO, CR, DZ, EC, EG, ET, GE, GY, HK, ID, IL, IN, IQ, IR, JO, JP, KR, KW, KZ, LB, LK, LY, MA, MN, MU, MX, MY, NG, NP, NZ, OM, PA, PE, PH, PK, PR, PS, QA, RE, RU, SA, SG, SV, SY, TH, TN, TR, TT, TW,

UA, VN, ZA.

Total Product Life Cycle TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = DWC and Original Applicant = SORIN GROUP DEUTSCHLAND GMBH[29]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=71593
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K052601
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DWC
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DWC
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=DWC
28. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.55
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=DWC&knumber=&applicant=SORIN%20GROUP%20DEUTSCHLAND%20GMBH

EXHIBIT "E"

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

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

Customer Name
Address
City, State Zip

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

Affected Devices: Sorin Group Perfusion System –Heater Cooler 3T devices (refer to Attachment 1 for affected catalog and serial numbers)

Date: 15 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.

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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 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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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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✓ 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 Technical Service Support at 1-800-221-7943 ext 6355
✓ 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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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).
- ✓ 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, immediately contact your infection control manager to determine appropriate actions
- ✓ 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.
  - o For emergency surgeries please consult your infection control manager to determine appropriate actions.

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For technical support please contact the Technical Services hotline at 1-800-221-7943 X6355.

Please complete and return the attached Confirmation Form (see **Attachment 3**) by fax to 303-467-6502 or by email to yvonne.feyerherm@sorin.com.

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 Amritt Khorran at 303-467-6306 or Yvonne Feyerherm at 303-467-6503 or by email to amritt.khorran@sorin.com or yvonne.feyerherm@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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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
16-02-80	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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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:

Product Code	Product description	Affected Serial Number

Please correct any inaccurate information above.

Please return this completed form to:
Yvonne Feyerherm by email: yvonne.feyerherm@sorin.com or by fax (303) 467-6502.

Section 1 - Please Complete:
We HAVE reviewed and understand the attached Field Safety Notice ☐ Yes ☐ No

We DO NOT understand the attached Field Safety Notice and request more information ☐ Yes ☐ No

WE HAVE discarded the old Instruction for Use ☐ Yes ☐ No

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

Submitted by _____
Signature _____ Date _____/_____/_____

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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.

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

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

SORIN GROUP
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Geschäftsführer:
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Giulio Cordano

Amtsgericht München
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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
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Cc:
Thierry Dupoux
Vice President of Quality Assurance and Regulatory Affairs
LivaNova (formerly Sorin Group Deutschland GmbH)
Lindberghstrasse 25
Munchen, 80939
Germany

Carrie Wood
Director
Customer Quality
LivaNova (formerly Sorin Group USA)

14401 W 65th Way
Arvada, CO 80004

More in 2015
(/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Magaly De La Cruz Gonzalez, individually and on behalf of her minor daughter, Genesis De La Cruz,

(b) County of Residence of First Listed Plaintiff Lafourche Parish
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Mark E. Jaffe, Esq., Plotkin, Vincent & Jaffe, L.L.C.
111 Veterans Memorial Blvd. Suite 520 Metairie, LA 70005
(504) 267-6195

DEFENDANTS

Sorin Group Deutschland GMBH and Sorin Group USA, Inc., d/b/a Liva Nova PLC,

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☒ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
Diversity of Citizenship 28-USC-1332

Brief description of cause:
Product liability involving defective Stockert 3T heart-lung device

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE June 25, 2018

SIGNATURE OF ATTORNEY OF RECORD Mark E Jaffe

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

Magaly De La Cruz Gonzalez, individually and on behalf of her minor daughter, Genesis De La Cruz,

Plaintiff(s)

v.

Sorin Group Deutschland GMBH and Sorin Group USA, Inc., d/b/a Liva Nova PLC,

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Sorin Group Deutschland GMBH d/b/a Liva Nova PLC
5 Merchant Square, North Wharf Rd.
London, United Kingdom
W21AY

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Mark E. Jaffe, Esq.,
Plotkin, Vincent & Jaffe, L.L.C.
111 Veterans Memorial Blvd. Suite 520
Metairie, LA 70005

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

Magaly De La Cruz Gonzalez, individually and on behalf of her minor daughter, Genesis De La Cruz,

Plaintiff(s)

v.

Sorin Group Deutschland GMBH and Sorin Group USA, Inc., d/b/a Liva Nova PLC,

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Sorin Group USA, Inc. (also d/b/a Liva Nova PLC)
14401 W. 65th Way
Arvada, CO 60004

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Mark E. Jaffe, Esq.,
Plotkin, Vincent & Jaffe, L.L.C.
111 Veterans Memorial Blvd. Suite 520
Metairie, LA 70005

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

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Signature of Clerk or Deputy Clerk

Civil Action No.

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was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset