UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS

BENJI NELSON, INDIVIDUALLY, AS PERSONAL REPRESENTATIVE OF THE ESTATE OF TERRY GENE NELSON, DECEASED, **Plaintiff,** **v.** **LIVANOVA PLC, SORIN GROUP DEUTSCHLAND GMBH; AND SORIN GROUP USA, INC.** **Defendants.**	**Civil Action No. _____** **COMPLAINT AND JURY DEMAND**

COMPLAINT

For her Complaint against Defendants, Plaintiff Benji Nelson, Individually, and as Personal Representative of the Estate of Terry Gene Nelson, states and alleges as follows:

INTRODUCTION AND PARTIES

1.

By this action Plaintiffs seek to recover damages caused by Terry Gene Nelson's exposure to non-tuberculous mycobacteria during heart transplant at Baylor University Medical Center in Dallas, Texas originating from a defective and unreasonably dangerous Sorin 3T Heater/Cooler System manufactured, distributed and sold by Defendants, as more particularly described below.

2.

Terry Nelson and Benji Nelson were, and at all material times husband and wife, residing in Bedford, Tarrant County, Texas, and are citizens of the State of Texas.

3.

Defendant LivaNova PLC ("LivaNova") is a foreign for-profit corporation incorporated under the laws of England and Wales with a headquarters in Milan, Italy and principal place of business located at 20 Eastbourne Terrace, London, W2 6LG. LivaNova is a global medical device company specializing in, among other products, devices used in the treatment of cardiovascular diseases. LivaNova, pursuant to a merger agreement between Sorin Group S.p.A.[1] and non-party, Cybertonics, Inc., advised purchasers in the United States that it is the responsible party for Sorin 3T System. Further, LivaNova was the recipient of various communications from the FDA regarding safety concerns about the Sorin 3T System.

4.

Upon information and belief, Defendant Sorin Group Deutschland GMBH ("Sorin") is a foreign for-profit corporation, with headquarters in Munich, Germany and principal place of business located at Lindberghstrasse 25, Munich, Germany 80938. Sorin designed, manufactured and marketed the Sorin 3T Heater-Cooler System used in Terry Nelson's surgical procedure in Dallas, Texas.

5.

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. Plaintiffs are under the information and belief that Defendants Sorin and Sorin USA are wholly-owned subsidiaries of LivaNova PLC, a British corporation ("LivaNova"). Defendant Sorin Group USA, Inc. may be served through its

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

agent of record, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201-3136.

6.

Each of the Defendants is a citizen of a state or foreign country other than Texas. At all relevant times, Defendants were the representatives, agents, employees, co-conspirators, servants, employees, partners, joint-venturers, franchisees, or alter egos of the other Defendants and were acting within the scope of such authority in such conspiracy, service, agency, employment, partnership, joint venture and/or franchise.

7.

Each Defendant was involved, either directly or as described in the paragraph above, in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, medical devices, including the Sorin 3T Heater/Cooler System, as well as monitoring and reporting adverse events.

JURISDICTION AND VENUE

8.

Plaintiffs reallege Paragraphs 1-7 above to the same extent as though fully set forth herein.

9.

This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which Plaintiffs reside.

10.

This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §1332.

11.

Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiffs' claims occurred, in part, in this District, and because Defendants conducted regular business in this District.

FACTS CONCERNING SORIN 3T SYSTEM

12.

Plaintiffs reallege Paragraphs 1-11 above to the same extent as though fully set forth herein.

13.

The Defendants market and sell thermal regulator devices to be used on patients in the operating room, including the Sorin 3T Heater-Cooler System ("Sorin 3T System").

14.

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

15.

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").

16.

Before commercial distribution in the United States of the Sorin 3T System, the Defendants submitted a 510K premarket notification of intent to market the Sorin 3T System with the Secretary

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

17.

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 the Quality Systems Regulation (21CPR part 820); and if applicable, the Electronic Product Radiation Control Provisions (Sections 531-542 of the Act); 21CFR 10001050."

18.

Beginning in 2014 at the latest, numerous hospitals began reporting and announcing that surgery patients had tested positive for a rare non-tuberculous mycobacterium (“NTM”), leading to many deaths and life-threatening illnesses.

19.

NTM is a heterogeneous group of bacteria composed of many species in the family of

mycobacteria. NTM are ubiquitous organisms commonly found in the soil and natural water sources. If allowed within the operative field, it poses a significant health risk to surgical patients and to patients who are immunodeficient.

20.

NTM can take anywhere from weeks to years before it manifests into a non-tuberculous mycobacterium infection.

21.

Tissue that has been infected with NTM 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."

22.

Diagnosis of NTM can be made from a laboratory analysis of a sample or biopsy of the infected area. In severe cases, the mycobacterium can be found in the blood and isolated from a blood sample. Targeted cultures, screenings, and proper testing are usually not done unless the physician has been made aware of this type of mycobacterium exposure.

23.

Death is always a serious risk of this type of infection; and treatments, which include draining collections of puss or removing infected tissue, coupled with rigorous administration of a series of aggressive and potentially toxic antibiotics for prolonged periods of time, also introduce enhanced risks of death and more permanent and substantial impairment and disability.

24.

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."

25.

The recall instructed all affected customers to follow *new* Instructions for Use, which were outlined in the June 15, 2015 Field Safety Notice Letter for EU English-speaking countries, followed up by a similar letter to users in the United States on August 6, 2015, both issued by Christian Peis, the Director of Quality Assurance for Sorin.

26.

Sorin indicated that it was providing the Field Safety Notice Letters 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

(a) [To] provide [affected users] with updated instructions for use regarding disinfection and maintenance procedures.

27.

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

28.

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

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

29.

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 Terry Nelson, all of which are violations of Federal and Texas State requirements.

30.

In violation of Federal and Texas 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, have 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.

31.

Defendants knew prior to 2015, and continue to know, that its disclosures to the FDA, the public, and Plaintiff 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 by Duane, as more fully described herein.

32.

In violation of Federal and State requirements, 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.

33.

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

34.

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

35.

The Defendants provided incomplete, insufficient, and misleading instructions, training, and information to hospitals and physicians, which is in direct violation of Federal and State requirements 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.

36.

The Sorin 3T System used during Terry Nelson's 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.

37.

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.

CASE SPECIFIC FACTUAL ALLEGATIONS

38.

On May 18, 2016, Terry Nelson underwent a heart transplant at Baylor University Medical Center, wherein the surgical team used the device to assist in the cooling and rewarming of his blood; and the surgical procedure accomplished the goals of the surgical team, leading to his subsequent discharge from the hospital.

39.

Over the weeks and months post-transplant, Terry was treated for crypto pneumonia, recurrent crypto meningitis, nocardia pneumonia and atypical mycobacterial infection in the lung. He was admitted to Baylor University Medical Center on September 12, 2016 wherein cultures were positive for NTM.

40.

Terry Nelson's condition continued to gravely deteriorate and as a result he was again admitted to Baylor University Medical Center on January 2, 2017 for treatment of acute respiratory failure and multiple other issues. The records reveal there was a high probability of imminent or life-threatening deterioration in Terry's condition.

41.

Terry Nelson's condition continued to gravely deteriorate to an alarming extent placing him at a risk of death. He became critically ill, developed multiorgan failure and ultimately died on February 27, 2017.

42.

The injuries, conditions, and complications Terry suffered due to the defective Sorin 3T

System include, but are not limited to, multiple organ failure, excruciating pain, weakness, excessive additional and debilitating medical treatment, suffering, and permanent disability and injury resulting in his death.

COUNT 1 - NEGLIGENCE

43.

Plaintiffs reallege Paragraphs 1-42 above to the same extent as though fully set forth herein.

44.

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

45.

The Defendants breached this duty by designing, labeling, manufacturing, assembling, inspecting, testing, marketing, distributing, instructing, and selling the Sorin 3T System in a defective and unreasonably unsafe condition including, but not limited to, its propensity for the colonization of organisms, including NTM.

46.

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 Plaintiff of a defect once it was discovered. The Defendants violated these duties when they failed to do so, which further placed Plaintiffs at risk for harm and injury.

47.

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 Baylor University Medical Center during Terry Nelson's heart procedure was done in violation of those requirements.

48.

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 they failed to comply therewith and deviated from the statutory requirements.

49.

As a direct and proximate result of Defendants' violations and failure to exercise ordinary care, Plaintiffs have suffered severe debilitating injuries, economic loss, and other damages, including, but not limited to, cost of medical care, rehabilitation, lost income, loss of consortium, and pain and suffering.

50.

Under Texas law, the Defendants' violations of said Federal statutes and regulations constitute negligence per se.

COUNT II- STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

51.

Plaintiffs reallege Paragraphs 1-50 above to the same extent as though fully set forth herein.

52.

Defendants are strictly liable in tort for the sale of the product in a defective condition or unreasonably dangerous condition, along with Defendants' violations of federal regulations as outlined herein.

53.

At all times material hereto, Defendants were the manufacturers, designers, researchers, distributors, sellers, and/or suppliers of the Sorin 3T System and placed it in the stream of commerce in a condition which rendered it unreasonably dangerous due to its propensity to expose patients to intraoperative infection. The subject product was unreasonably dangerous in construction or composition.

54.

Alternatively, the Sorin 3T System purchased and utilized in Plaintiff's care and treatment was defective because it varied from Defendants' intended design and contained unreasonably dangerous conditions.

55.

As a direct and proximate result of the defective condition of the Sorin 3T System, Plaintiffs have suffered severe, debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, pain and suffering, loss of consortium, and death.

56.

As a direct and proximate result of Defendants' violations of Federal and State laws, Plaintiffs have suffered severe, debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, pain and suffering, loss of consortium, and death.

57.

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.

58.

As a direct and proximate result of Defendants' breach of the aforementioned implied warranties and violations of Federal and State laws, Plaintiffs have suffered severe, debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, pain and suffering, loss of consortium, and death.

COUNT III- STRICT PRODUCTS LIABILITY – DESIGN DEFECT

59.

Plaintiffs reallege Paragraphs 1-58 above to the same extent as though fully set forth herein.

60.

At all times herein mentioned, Defendants are the researchers, designers, manufacturers, testers, advertisers, promoters, marketers, packagers, labelers, sellers and/or distributors of the Sorin 3T System, which is defective and unreasonably dangerous.

61.

The Sorin 3T System is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. The Sorin 3T System is defective in design because it lacks efficacy, poses a greater likelihood of injury, is more dangerous than other available systems indicated for similar conditions and uses, and the utility of the Sorin 3T System does not outweigh its risks.

62.

The defective condition of the Sorin 3T System rendered it unreasonably dangerous and/or not reasonably safe, and the Sorin 3T System was in this defective condition at the time it left the hands of Defendants. The Sorin 3T System was expected to and did reach Decedent and his physician without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

63.

The Sorin 3T System was used for its intended purposes and the product was not materially altered or modified prior to its use.

64.

The Sorin 3T System is defective in design because of its propensity to cause patients unnecessarily 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

65.

The Sorin 3T System is defective in design because the increased risk for complication rates, including rates of NTM infection, at an unreasonably greater rate than other heater cooler systems.

66.

At or before the time the Sorin 3T System was released on the market and/or utilized by Terry Nelson, Defendants could have designed the Sorin 3T System to make it less prone to infection exposure, and there was a practical, technically feasible safer alternative design that would have prevented the harm Mr. Nelson suffered without substantially impairing the function

of the device.

67.

Terry Nelson was not able to discover, nor could he have discovered through the exercise of reasonable diligence, the defective nature of the Sorin 3T System. Further, in no way could Plaintiffs have known that Defendants had designed, developed, and manufactured the Sorin 3T System in a way as to make the risk of harm or injury outweigh any therapeutic benefits.

68.

The Sorin 3T System is and was being used in the Defendants' intended manner at the time it was utilized intraoperatively with Terry Nelson.

69.

Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use and breached this duty.

70.

Defendants knew or should have known that the Sorin 3T System would be implanted in patients and that physicians and patients were relying on them to furnish a suitable product. Further, Defendants knew or should have known that patients in whom the Sorin 3T System would be used, such as Mr. Nelson, could be and would be affected by the defective design of the Sorin 3T System.

71.

Defendants researched, designed, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Mr. Nelson, and Defendants are therefore strictly liable for the injuries sustained by Plaintiffs.

72.

As a direct and proximate result of Defendants' placement of the defective Sorin 3T System into the stream of commerce and Terry Nelson use of the defective Sorin 3T System as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants, Plaintiffs suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT III- STRICT PRODUCTS LIABILITY – FAILURE TO WARN

73.

At all times material hereto, Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, marketed, sold to patients and/or introduced the Sorin 3T System into the stream of commerce knowing the system would then be utilized with patients intraoperatively. In the course of the same, Defendants directly advertised and/or marketed the product to health care professionals and consumers, including Plaintiff and Plaintiff's physicians, and therefore had a duty to warn of the risks associated with the use of the Sorin 3T System. Defendants breached this duty.

74.

The Sorin 3T System was not accompanied by proper warnings and instructions to physicians and the public regarding potential adverse side effects associated with the utilization of the Sorin 3T System and the comparative severity and duration of such adverse side effects.

75.

The warnings, instructions, and information provided to the medical community and the public did not accurately reflect the symptoms, scope, or severity of potential side effects, specifically the risk of NTM infection.

76.

The Sorin 3T System was defective due to inadequate warnings, information, and instructions that failed to convey to physicians and the public accurate information about the scope and severity of potential side effects.

77.

Had Defendants reasonably and properly provided adequate warnings, such warnings would have been heeded and no healthcare professional, including Plaintiff's physicians, would have used the Sorin 3T System, and no consumer, including Plaintiffs, would have undergone surgical procedures utilizing the Sorin 3T System.

78.

As a direct and proximate result of Defendants' conduct, Plaintiffs suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT III- BREACH OF EXPRESS AND IMPLIED WARRANTIES

79.

Plaintiffs reallege Paragraphs 1-78 above to the same extent as though fully set forth herein.

80.

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.

81.

When the Sorin 3T System was used during Terry Nelson's heart procedure, the system was being used for the original purposes for which it was approved and intended.

82.

Terry Nelson, individually and/or by and through his healthcare provider, relied upon Defendants' express and implied warranties in consenting to have the heart procedure performed with assistance of the Sorin 3T System.

83.

Defendants breached these express and implied warranties because the Sorin 3T System was neither merchantable nor suited for the intended uses as warranted.

84.

Defendants' breach of its express and implied warranties resulted in the use of an unreasonably dangerous and defective product during Terry's heart procedure, placing Terry Nelson's life, health and safety in jeopardy.

85.

As a direct and proximate result of Defendants' breach of the aforementioned implied warranties and violations of Federal and State laws, Plaintiffs have suffered severe, debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, pain and suffering, loss of consortium, and death.

COUNT IV- NEGLIGENT MISREPRESENTATION

86.

Plaintiffs reallege Paragraphs 1-85 above to the same extent as though fully set forth herein.

87.

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

88.

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

89

Had the Defendants accurately and truthfully represented to the FDA, the medical community, Plaintiffs, and the public, the material facts relating to the risks of the Sorin 3T System, Plaintiffs and/or Plaintiffs' healthcare provider would not have utilized the Sorin 3T System it did during Terry Nelson's heart procedure.

90.

Under Texas law, the Defendants' violations of said Federal statutes and regulations constitute negligent misrepresentation.

91.

As a direct and proximate result of Defendants' breach of the aforementioned implied warranties and violations of Federal and State laws, Plaintiffs have suffered severe, debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, pain and suffering, loss of consortium, and death.

COUNT V- MISREPRESENTATION BY OMISSION

92.

Plaintiffs reallege Paragraphs 1-91 above to the same extent as though fully set forth herein.

93.

Throughout the relevant time period, Defendants knew that the Sorin 3T System was

defective and unreasonably unsafe for intended purposes, which the Defendants failed to properly report to the FDA.

94.

The Defendants were under a duty to disclose to the FDA, Plaintiffs, and the medical community, the defective nature and extent of adverse reactions and labeling errors of the system because the Defendants were in a superior position to know the true quality, safety, and efficacy of the Sorin 3T System.

95.

The Defendants concealed from and/or failed to disclose to the FDA, Plaintiffs, Plaintiffs' healthcare providers, and the medical community that its Sorin 3T System was defective, unsafe, and unfit for the purposes intended, and that it was not of merchantable quality.

96.

The facts concealed and/or not disclosed to the FDA, Terry, or the medical community were material facts that a reasonable person would have considered important in deciding whether to utilize the Sorin 3T System, and were facts that were required to be disclosed pursuant to Federal and State statutes and regulations.

97.

Under Texas law, the Defendants' violations of said Federal statutes and regulations constitute misrepresentation by omission.

98.

As a direct and proximate result of Defendants' breach of the aforementioned implied warranties and violations of Federal and State laws, Plaintiffs have suffered severe, debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income,

pain and suffering, loss of consortium, and death.

COUNT VI- VIOLATIONS OF THE TEXAS DECEPTIVE TRADE PRACTICES ACT

99.

Plaintiffs reallege Paragraphs 1-98 above to the same extent as though fully set forth herein.

100.

At all times relevant to this action, the Texas Deceptive Trade Practices Act, codified in Chapter 17 of the Texas Business and Commerce Code, was in effect and Plaintiff are consumers as defined therein.

101.

The Defendants have engaged in deceptive acts or practices in violation of the Texas Deceptive Trade Practices Act, 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.

102.

Defendants' deceptive acts and practices occurred during a course of conduct involving trade or commerce and Plaintiffs relied on these representations herein to their detriment.

103.

As a direct and proximate result of Defendants' breach of the aforementioned implied warranties and violations of Federal and State laws, Plaintiffs have suffered severe, debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, pain and suffering, loss of consortium, and death.

COUNT VII- LOSS OF CONSORTIUM

104.

Plaintiffs reallege Paragraphs 1-103 above to the same extent as though fully set forth herein.

105.

As a direct and proximate result of the Defendants' deviations from the applicable standards of care as expressed herein, Benji Nelson has been, and will continue to be, deprived of the consortium, society, comfort, protection, and services of her husband, thereby causing and continuing to cause economic damages, grief, sorrow, mental anguish, emotional distress, and pain and suffering and prays for judgment against the Defendants as set forth in this Complaint.

DISCOVERY RULE AND TOLLING

106.

Plaintiffs reallege Paragraphs 1-105 above to the same extent as though fully set forth herein.

107.

Plaintiffs assert all applicable Texas statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

108.

Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have discovered facts establishing that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

109.

Despite diligent investigation by Plaintiffs into the cause of their injuries, including consultations with Plaintiffs' medical providers, the nature of Plaintiffs' injuries and damages, and their relationship to the System was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

110.

The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiffs' physicians of the true risks associated with the System. As a result of Defendants' fraudulent concealment, Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

ACTUAL DAMAGES

111.

Plaintiffs reallege Paragraphs 1-110 above to the same extent as though fully set forth herein.

112.

As a direct and proximate result of the acts, omissions, and violations of the Defendants alleged herein, Plaintiffs suffered injuries and damages, including without limitation; physical

pain and suffering of a past, present and future nature; emotional pain and suffering of a past, present and future nature; permanent impairment and scarring; medical bills and expenses of a past, present and future nature; loss of earnings; loss of earning capacity; loss of enjoyment of life; pre-and post-judgment interest; statutory and discretionary costs; and loss of consortium.

PUNITIVE DAMAGES

113.

Plaintiffs reallege Paragraphs 1-112 above to the same extent as though fully set forth herein.

114.

The acts, omissions, and violations of the Defendants as set forth herein constitute intentional, fraudulent, malicious and/or reckless conduct. Accordingly, Plaintiffs are entitled to an award of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, individually and collectively, jointly and severally, as follows:

(a) Trial by jury;

(b) Judgment against Defendants for all compensatory allowable to Plaintiffs;

(c) Judgment against Defendants for all other relief sought by Plaintiffs under this Complaint;

(d) Judgment against Defendants for exemplary damages;

(e) For reasonable attorneys' fees and costs;

(f) For pre-judgment interest; and

(g) For such further and other relief the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: October 30, 2018

Respectfully submitted,

VAN WEY LAW, PLLC

/s/ Kay L. Van Wey

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Counsel for Plaintiffs

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

BEJI NELSON, INDIVIDUALLY, AS PERSONAL REPRESENTAIVE OF THE ESTATE OF TERRY GENE NELSON, DECEASED

(b) County of Residence of First Listed Plaintiff Tarrant County, Texas
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Kay L. Van Wey, Van Wey Law, PLLC, 12720 Hillcrest Road, Suite 725, Dallas, TX 75230 - Tel: (214) 329-1350 - Fax (800) 582-1042

DEFENDANTS

LIVANOVA PLC, SORIN GROUP DEUTSCHLAND GMBH; AND SORIN GROUP USA, INC.

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	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
❒ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	☒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		❒ 820 Copyrights	❒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	❒ 830 Patent	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	❒ 370 Other Fraud	❒ 710 Fair Labor Standards Act	❒ 835 Patent - Abbreviated New Drug Application	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 371 Truth in Lending	❒ 720 Labor/Management Relations	❒ 840 Trademark	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 380 Other Personal Property Damage	❒ 740 Railway Labor Act	SOCIAL SECURITY	❒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 385 Property Damage Product Liability	❒ 751 Family and Medical Leave Act	❒ 861 HIA (1395ff)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury		❒ 790 Other Labor Litigation	❒ 862 Black Lung (923)	❒ 490 Cable/Sat TV
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 791 Employee Retirement Income Security Act	❒ 863 DIWC/DIWW (405(g))	❒ 850 Securities/Commodities/ Exchange
❒ 196 Franchise				❒ 864 SSID Title XVI	❒ 890 Other Statutory Actions
				❒ 865 RSI (405(g))	❒ 891 Agricultural Acts
					❒ 893 Environmental Matters
					❒ 895 Freedom of Information Act
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	❒ 896 Arbitration
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	Habeas Corpus:	❒ 462 Naturalization Application	❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 220 Foreclosure	❒ 441 Voting	❒ 463 Alien Detainee	❒ 465 Other Immigration Actions	❒ 871 IRS—Third Party 26 USC 7609	❒ 950 Constitutionality of State Statutes
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 510 Motions to Vacate Sentence			
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 530 General			
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	❒ 535 Death Penalty			
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	Other:			
	❒ 448 Education	❒ 540 Mandamus & Other			
		❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

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)***:
28 U.S.C. § 1332 (Diversity)

Brief description of cause:
Products Liability, Personal Injury

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
10/30/2018

SIGNATURE OF ATTORNEY OF RECORD
/s/ Kay L. Van Wey

FOR OFFICE USE ONLY

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

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If a related case exists, whether pending or closed, insert the docket numbers and the corresponding judge names for such cases. A case is related to this filing if the case: 1) involves some or all of the same parties and is based on the same or similar claim; 2) involves the same property, transaction, or event; 3) involves substantially similar issues of law and fact; and/or 4) involves the same estate in a bankruptcy appeal.

Date and Attorney Signature. Date and sign the civil cover sheet.