IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

EDWARD BAKER and JACK MILLER, on behalf of themselves and all others similarly situated,	:	Civil Action No. 1:16-CV-00260
Plaintiffs,	:	Judge John E. Jones, III
v.	:	Filed Electronically
SORIN GROUP DEUTSCHLAND GMBH and SORIN GROUP USA, INC.,	:	
Defendants.	:	

DEFENDANTS' ANSWER AND DEFENSES TO PLAINTIFFS' FIRST AMENDED CLASS ACTION COMPLAINT

Defendants Sorin Group Deutschland GmbH ("Sorin Deutschland") and Sorin Group USA, Inc. ("Sorin USA") (collectively, "Defendants"), for their Answer and Defenses to the First Amended Class Action Complaint ("FAC") of Plaintiffs Edward Baker and Jack Miller ("Plaintiffs"), respond as follows:

Defendants deny each and every allegation, claim, and thing contained in Plaintiffs' FAC, except as hereafter expressly admitted, qualified, or explained.

NATURE OF THE ACTION

1. Defendants admit that Plaintiffs bring this action individually and seek to bring it also on behalf of "all persons similarly situated." Defendants deny

that Plaintiffs' claims are appropriate for treatment as a class action, deny that paragraph 1 of the FAC accurately describes the Plaintiffs or a potential class, and deny all remaining allegations in paragraph 1 of the FAC.

2. Defendants deny the allegations in paragraph 2 of the FAC.

3. Defendants deny the allegations in paragraph 3 of the FAC.

4. Defendants admit that Plaintiffs seek the relief stated in paragraph 4 of the FAC, but deny that they are entitled to this relief and deny any remaining allegations in paragraph 4.

JURISDICTION AND VENUE

5. Based on Plaintiffs' allegations about their citizenship and residency, Defendants admit that there is subject matter jurisdiction over this action pursuant to the diverse citizenship of the parties, for purposes of this case only. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations about Plaintiffs' citizenship and residency and therefore deny them. Defendants admit LivaNova PLC ("LivaNova") is a foreign corporation incorporated under the laws of England and Wales with a headquarters in London, United Kingdom. Defendants admit Sorin Deutschland is a foreign corporation headquartered in Munich, Germany. Defendants admit Sorin USA has a principal place of business in Arvada, Colorado. Defendants admit that Sorin USA has sold the 3T Heater-Cooler System ("3T System") to WellSpan York Hospital

("WellSpan") and Penn State Milton S. Hershey Medical Center ("Hershey"), but lack knowledge or information sufficient to form a belief as to the truth or falsity of allegations about how and when these devices were used in operating rooms where cardiac surgery occurred, and therefore deny the allegations that Sorin USA is the distributor of "the medical device at issue" in this case. Defendants deny any remaining allegations in paragraph 5 of the FAC.

6. Defendants deny that personal jurisdiction exists over LivaNova. Defendants admit that Sorin Deutschland is subject to personal jurisdiction in this District for purposes of this case only. Defendants admit the amount in controversy in this action exceeds $75,000. Defendants deny any remaining allegations in paragraph 6 of the FAC.

7. Plaintiffs' allegations in the first sentence of paragraph 7 raise a legal question to which no answer is needed. Assuming the allegations in the first sentence raise factual issues for which an answer is appropriate, Defendants admit that Plaintiffs' allegations of a purported class action meet the requirements of federal diversity jurisdiction under 28 U.S.C. § 1332(d), but Defendants deny the merits of Plaintiffs' allegations. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the alleged number of putative class members and their citizenship and residency, which are contained in paragraph 7 of the FAC, and therefore deny these allegations. Defendants deny

that the aggregate of the Class Members' claims is more than $5 million dollars, exclusive of interests and costs, and deny all remaining allegations in paragraph 7 of the FAC.

8. Defendants admit that venue is proper in this District, for purposes of this case only. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the location of the activities giving rise to Plaintiffs' claims and therefore deny them. Defendants deny all remaining allegations in paragraph 8 of the FAC.

THE PARTIES

9. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in the first two sentences of paragraph 9 of the FAC and therefore deny them. Defendants deny the allegations in the third sentence of paragraph 9 of the FAC and deny any remaining allegations in paragraph 9 of the FAC.

10. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in the first two sentences of paragraph 10 of the FAC and therefore deny them. Defendants deny the allegations in the third sentence of paragraph 10 of the FAC and deny any remaining allegations in paragraph 10 of the FAC.

11. Defendants admit that LivaNova is a foreign for-profit company incorporated under the laws of England and Wales with a headquarters in London, United Kingdom and that it is a global medical device company specializing in medical devices used in the treatment of cardiovascular diseases. Defendants admit that LivaNova was formed for the purpose of facilitating the business combination of Sorin S.p.A. and Cyberonics, Inc. and admits that Sorin S.p.A. was the predecessor holding company of Sorin USA and Sorin Deutschland. Defendants admit that Exhibit B attached to the FAC is a letter from the FDA addressed to the Chief Executive Offer of "LivaNova (formerly Sorin Group S.p.A.), Via Benigono Crespi, 17, Milano, 20159, Italy," related to inspections that occurred at Sorin Deutschland and Sorin USA. Defendants deny the remaining allegations in paragraph 11 of the FAC and in its footnote.

12. Defendants admit that Sorin Deutschland is a foreign for-profit company headquartered in Munich, Germany. Defendants admit that Sorin Deutschland designed and marketed and is the registered manufacturer for the 3T System, in general. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 12 of the FAC related to the heater-cooler devices that were used in the Plaintiffs' and Class Members' surgeries, and therefore deny these allegations. Defendants deny all remaining allegations in paragraph 12 of the FAC.

13. Defendants admit Sorin USA has a principal place of business in Arvada, Colorado and has marketed and distributed the 3T System. Defendants admit that Sorin USA and Sorin Deutschland are wholly owned subsidiaries of LivaNova and that both Sorin USA and Sorin Deutschland market and sell products under the LivaNova brand. Defendants deny all remaining allegations in Paragraph 13 of the FAC.

GENERAL FACTUAL ALLEGATIONS

14. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 14 of the FAC and therefore deny them.

15. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 15 of the FAC and therefore deny them.

16. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 16 of the FAC and therefore deny them.

17. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 17 of the FAC and therefore deny them.

18. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 18 of the FAC and its footnote, and therefore deny them.

19. Defendants admit that nontuberculous mycobacterium ("NTM") occurs naturally in the environment and rarely causes illness. Defendants also admit that there are different types of NTM, which present different potential risks, which may vary in part based on the particular medical and health condition of an individual person. Defendants deny all remaining allegations in paragraph 19 of the FAC and in its footnote.

20. Defendants deny the allegations in paragraph 20 of the FAC.

21. Defendants admit the statements in paragraph 21 of the FAC describe possible conditions that can occur in certain individual circumstances, allege that there are different types of NTM and different general and individual presentations of infection and deny all remaining allegations in paragraph 21 of the FAC.

22. Defendants deny the allegations in paragraph 22 of the FAC.

23. Defendants allege there are different types of NTM and different general and individual presentations of infection. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 23 of the FAC about the means by which NTM is diagnosed in all these

potential situations, and therefore deny them. Defendants deny all remaining allegations in paragraph 23 of the FAC.

24. Defendants allege there are different types of NTM and different general and individual presentations of infection. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 24 of the FAC about the means by which NTM is treated in all these potential situations, and therefore deny them. Defendants deny all remaining allegations in paragraph 24 of the FAC.

25. Defendants allege there are different types of NTM and different general and individual presentations of infection, with differing prognoses, which may vary in part based on the particular medical and health condition of an individual person. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 25 of the FAC about the prognosis in all these potential situations, and therefore deny them. Defendants deny all remaining allegations in paragraph 25 of the FAC.

26. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 26 of the FAC and therefore deny them.

27. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 27 of the FAC and therefore deny them.

28. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 28 of the FAC and therefore deny them.

29. Defendants are aware of various public statements by the CDC about NTM contamination, which statements speak for themselves. Defendants deny any characterization of these statements. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 29 of the FAC and therefore deny them.

30. Defendants admit that on December 11, 2015, the Pennsylvania Department of Health issued a Health Advisory with the stated Subject of "Pennsylvania Department of Health (PADOH) and Pennsylvania Patient Safety Authority (PSA) Guidance Regarding Nontuberculous Mycobacterium (NTM) Infections among Patients Undergoing Open Heart Surgeries on Cardiopulmonary Bypass." Defendants admit paragraph 30 of the FAC contains some language from this document, which speaks for itself and should be read as a whole. Defendants deny any characterization of this document and deny any remaining allegations in paragraph 30 of the FAC and in its footnote.

31. Defendants deny the allegations in paragraph 31 of the FAC.

32. Defendants deny the allegations in paragraph 32 of the FAC.

33. Defendants admit that a Rapid Risk Assessment was published by the European Centre for Disease Prevention and Control on April 30, 2015, which identifies cases of infection caused by *Mycobacterium chimaera* that have been detected in patients having previously undergone cardiac surgery in Europe and cites in support four sources that were published in 2015. This document speaks for itself. Defendants deny the characterization of this document and deny all remaining allegations in paragraph 33 of the FAC and in its footnote.

34. Defendants admit that the footnote to paragraph 34 of the FAC refers to an article published in 2015, which article speaks for itself. Defendants deny the characterization of this article and deny all remaining allegations in paragraph 34 of the FAC.

35. Defendants admit that an article was published in July 2015 in the journal Clinical Infectious Diseases regarding patients with prosthetic valve endocarditis or vascular graft infection due to *M. chimaera.* This article speaks for itself. Defendants deny the characterizations of the article that are contained in paragraph 35 of the FAC and deny any remaining allegations in paragraph 35 of the FAC.

36. Defendants admit that an FDA Safety Communication dated October 15, 2015 stated that: "Between January 2010 and August 2015, the FDA received 32 Medical Device Reports (MDRs) of patient infections associated with heater-cooler devices or bacterial heater-cooler device contamination. Twenty-five of these MDRs were reported to the FDA in 2015. Some reports describe NTM infections related to cardiothoracic surgeries, but other reports do not specify the procedure the patient was undergoing. Eight reports were related to 3 events describing patient infections occurring in U.S. health care facilities. The remaining 24 reports involved health care facilities outside the United States, most of these in Western Europe. In some cases, patients presented with infections several months to years after their surgical procedures. It is important to note that half of the 32 reports submitted to the FDA describe bacterial contamination of the heater-cooler device without known patient involvement or infection. The FDA is not aware of NTM infections acquired by hospital staff." This document speaks for itself and should be read as a whole. Defendants deny the characterization contained in paragraph 36 of the FAC and deny any remaining allegations in paragraph 36 of the FAC.

37. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 37 of the FAC, based on the October 21, 2015 date, and therefore deny them. Defendants admit that on or

about October 27, 2015, the Centers for Disease Control and Prevention issued an Interim Practical Guidance to "(a) raise awareness among health departments, healthcare facilities, and healthcare providers of the possible association between NTM infections and use of heater-cooler devices . . ." This document speaks for itself, and Defendants deny the characterization contained in paragraph 37 of the FAC. Defendants deny any remaining allegations in paragraph 37 of the FAC.

38. Defendants admit that Sorin USA has sold 3T units to WellSpan and Hershey. As to these units, Defendants admit they were designed by Sorin Deutschland, the registered manufacturer of the 3T System, and marketed and sold by Sorin USA to these hospitals. Defendants deny all remaining allegations in paragraph 38 of the FAC.

39. Defendants admit that notice of a Class 2 Device Recall was posted by the Food and Drug Administration ("FDA") on or about July 15, 2015, and that the "Manufacturer Reason for Recall" was stated to be "Potential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per Instructions for Use." Defendants deny any characterization of this document, which speaks for itself, and deny any remaining allegations in paragraph 39 of the FAC.

40. Defendants admit that the document posted by FDA on or about July 15, 2015 listed as an "Action" that "Sorin Group issued a Field Safety Notice dated

June 15, 2015" and stated instructions customers were to follow, per that Notice. The FDA and Sorin documents speak for themselves, and Defendants deny any characterization of these documents. Defendants deny any remaining allegations in paragraph 40 of the FAC.

41. Defendants admit that a June 15, 2015 Field Safety Notice was signed by Christian Peis, Director of Quality Assurance for Sorin Group Deutschland GmbH, and that the contents of that document speak for themselves. Defendants deny Plaintiffs' characterization of the June 15, 2015 Field Safety Notice and deny all remaining allegations in paragraph 41 of the FAC.

42. Defendants deny the allegations in paragraph 42 of the FAC.

43. Defendants deny the allegations in paragraph 43 of the FAC.

44. Defendants admit that on December 11, 2015, the Pennsylvania Department of Health issued a Health Advisory with the stated Subject of "Pennsylvania Department of Health (PADOH) and Pennsylvania Patient Safety Authority (PSA) Guidance Regarding Nontuberculous Mycobacterium (NTM) Infections among Patients Undergoing Open Heart Surgeries on Cardiopulmonary Bypass." This document speaks for itself. Defendants deny the characterization of this document in paragraph 44 of the FAC and deny any remaining allegations in paragraph 44 of the FAC and in its footnote.

45. Defendants admit that paragraph 45 of the FAC contains some language from the December 11, 2015 Health Advisory issued by the PADOH. The Health Advisory speaks for itself and should be read as a whole. Defendants deny the characterization of the Health Advisory in paragraph 45 of the FAC and deny any remaining allegations in paragraph 45 of the FAC.

46. Defendants admit that paragraph 46 of the FAC contains some language from the December 11, 2015 Health Advisory issued by the PADOH. The Health Advisory speaks for itself and should be read as a whole. Defendants deny the characterization of the Health Advisory in paragraph 46 of the FAC and deny any remaining allegations in paragraph 46 of the FAC and in its footnote.

47. Defendants admit that paragraph 47 of the FAC contains some language from the December 11, 2015 Health Advisory issued by the PADOH, which is followed by a list of 13 additional "Differences included:" The Health Advisory speaks for itself and should be read as a whole. The Rapid Risk Assessment referenced in the footnote to paragraph 47 also speaks for itself. Defendants deny the characterization of the documents in paragraph 47 of the FAC and its footnote, and deny any remaining allegations in paragraph 47 of the FAC and in its footnote.

48. FDA has issued several public communications about the 3T System. These statements speak for themselves. Defendants deny any characterization of these statements and deny any remaining allegations in paragraph 48 of the FAC.

49. Defendants admit that on December 29, 2015, FDA issued a warning letter addressed to the Chief Executive Officer of "LivaNova (formerly Sorin Group S.p.A.), Via Benigono Crespi, 17, Milano, 20159, Italy" with respect to inspections at the Sorin Deutschland and Sorin USA facilities in Munich, Germany and Arvada, Colorado. This letter speaks for itself and Defendants deny the characterizations of the letter contained in paragraph 49 of the FAC. The footnote to paragraph 49 contains statements of law to which no answer is needed. Assuming the allegations in the footnote to paragraph 49 raise factual issues for which an answer is appropriate, Defendants deny them, and Defendants deny any remaining allegations contained in paragraph 49 of the FAC and in its footnote.

50. The December 29, 2015 letter speaks for itself, and Defendants deny the characterization of this letter in paragraph 50 of the FAC. Defendants deny any remaining allegations in paragraph 50 of the FAC.

51. The December 29, 2015 letter speaks for itself, and Defendants deny the characterization of this letter in paragraph 51 of the FAC. Defendants deny any remaining allegations in paragraph 51 of the FAC.

52. Defendants deny the implication in paragraph 52 of the FAC that patients were exposed "to the bacteria" or that hospitals said patients were exposed. Defendants lack knowledge or information sufficient to form a belief about the truth or falsity of the remaining allegations in paragraph 52 of the FAC and therefore deny them.

53. Defendants admit that as of October 19, 2016, a website at www.wellspan.org/yorkopenheart/patientinformation referenced various resources for "individuals who may have been exposed to this bacteria during your open-heart surgery at WellSpan York Hospital," which website says "we are committed to ensuring you receive all the information, care and treatment you need regarding this issue, at no cost to you." Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the actual services provided by WellSpan. Defendants deny any remaining allegations in paragraph 53 of the FAC and in its footnote.

54. Defendants deny that the web address cited in footnote 12 of the FAC contains the statements alleged in paragraph 54 of the FAC, but admit that this web address, as of October 19, 2016, links to an FAQ document stating that Hershey will provide medical treatment necessary to treat confirmed NTM infections associated with open-heart surgery. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the actual services provided

by Penn State Hershey. Defendants deny any remaining allegations in paragraph 54 of the FAC.

55. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 55 of the FAC.

56. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 56 of the FAC and therefore deny them.

57. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 57 of the FAC that relate to the Plaintiffs' knowledge as to replacement of 3T Systems by WellSpan and Hershey. Defendants deny the allegations in paragraph 57 of the FAC regarding the 3T devices and their design, and deny any remaining allegations in paragraph 57 of the FAC.

58. Defendants admit that hospitals in Pennsylvania do continue to use the 3T System and deny that this use places open heart surgery patients at significant risk of injury or death. Defendants deny any remaining allegations in paragraph 58 of the FAC.

CLASS ACTION ALLEGATIONS

59. The allegations in paragraph 59 of the FAC raise a legal question to which no answer is needed. Assuming the allegations in paragraph 59 raise factual

issues for which an answer is appropriate, Defendants admit that Plaintiffs purport to bring this action as a class action, but deny the merits of Plaintiffs' request. Defendants deny the remaining allegations in paragraph 59 of the FAC.

60. The allegations in paragraph 60 of the FAC raise a legal question to which no answer is needed. Assuming the allegations in paragraph 60 raise factual issues for which an answer is appropriate, Defendants admit that Plaintiffs purport to bring this action as a class action and seek such certification, but deny the merits of Plaintiffs' request.

61. The allegations in paragraph 61 of the FAC raise a legal question to which no answer is needed. Assuming the allegations in paragraph 61 raise factual issues for which an answer is appropriate, Defendants admit that Plaintiffs purport to bring this action as a class action and seek such certification, but deny the merits of Plaintiffs' request.

62. The allegations in paragraph 62 of the FAC raise legal questions to which no answer is needed. Assuming the allegations in paragraph 62 raise factual issues for which an answer is appropriate, Defendants state that they lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 62 concerning the number of individuals undergoing open heart surgery during the relevant time frame and concerning Plaintiffs' individual

heart surgeries, and therefore deny them. Defendants deny the remaining allegations in paragraph 62 of the FAC, including all subparts.

TOLLING OF THE STATUTE OF LIMITATIONS
Discovery Rule

63. The allegations in paragraph 63 of the FAC raise a legal question to which no answer is needed. If the allegations in paragraph 63 raise factual issues for which an answer is appropriate, Defendants deny them.

64. The allegations in paragraph 64 of the FAC raise a legal question to which no answer is needed. If the allegations in paragraph 64 raise factual issues for which an answer is appropriate, Defendants deny them.

65. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 65 of the FAC and therefore deny them.

66. Defendants deny the allegations in paragraph 66 of the FAC.

COUNT I
MEDICAL MONITORING
Plaintiffs v. All Defendants

67. Defendants incorporate by reference the preceding paragraphs as if fully set forth herein.

68. Defendants allege that there are different types of NTM with different general and individual periods of latency, and deny the allegations in paragraph 68 of the FAC.

69. Defendants deny the allegations in paragraph 69 of the FAC.

70. Defendants deny the allegations in paragraph 70 of the FAC.

71. Defendants deny the allegations in paragraph 71 of the FAC, including all its subparts.

72. Defendants deny the allegations in paragraph 72 of the FAC.

73. Defendants deny the allegations in paragraph 73 of the FAC.

74. Defendants deny the allegations in paragraph 74 of the FAC.

75. Defendants deny the allegations in paragraph 75 of the FAC.

76. Defendants deny the allegations in paragraph 76 of the FAC.

COUNT II
DECLARATORY RELIEF PURSUANT TO 28 U.S.C. § 2201, *ET SEQ.*
Plaintiffs v. All Defendants

77. Defendants incorporate by reference the preceding paragraphs as if fully set forth herein.

78. The allegations in paragraph 78 of the FAC raise a legal question to which no answer is needed. If the allegations in paragraph 78 raise factual issues for which an answer is appropriate, Defendants admit that paragraph 78 quotes an excerpt from the Federal Declaratory Judgments Act, 28 U.S.C. § 2201, but deny that Plaintiffs are entitled to declaratory relief under this statute.

79. The allegations in paragraph 79 of the FAC raise a legal question to which no answer is needed. If the allegations in paragraph 79 raise factual issues for which an answer is appropriate, Defendants deny them.

80. The allegations in paragraph 80 of the FAC raise a legal question to which no answer is needed. If the allegations in paragraph 80 raise factual issues for which an answer is appropriate, Defendants admit that Plaintiffs allege the 3T System is defective, but deny that the 3T System is defective under any applicable legal definition. Defendants also deny that the term "defective" has a legally applicable meaning separate and removed from the context of any particular cause of action for which defect is an element, and deny that it is appropriate or meaningful to declare a product defective in the context of this medical monitoring action. Defendants deny any remaining allegations in paragraph 80 of the FAC.

81. The allegations in paragraph 81 of the FAC raise a legal question to which no answer is needed. If the allegations in paragraph 81 raise factual issues for which an answer is appropriate, Defendants deny that the 3T System is defective or has defects under any applicable legal definition of those terms, and deny that they failed to adequately warn of the alleged "risk of bacterial colonization in their 3T System." Defendants also deny that the terms "defect" or "defective" have a legally applicable meaning separate and removed from the context of any particular cause of action for which defect is an element and deny

that it is appropriate or meaningful to declare a product defective in the context of this medical monitoring action. Defendants also deny that Plaintiffs are entitled to recover any damages, monitoring or other relief from Defendants, because Plaintiffs cannot meet their burden to prove the elements needed to support such recovery. Defendants also deny that the question of liability to other persons is appropriate for consideration in a class action. Defendants deny any remaining allegations in paragraph 81 of the FAC.

82. Defendants deny the allegations in paragraph 82 of the FAC.

83. Defendants admit that Plaintiffs seek the declaration stated in paragraph 83 of the FAC but deny that Plaintiffs are entitled to such declaration. Defendants also deny that such declaration is appropriate for consideration in a class action, deny that the 3T System is defective, deny that the term "defective" has a legally applicable meaning separate and removed from the context of any particular cause of action for which defect is an element, deny that it is appropriate or meaningful to declare a product defective in the context of this medical monitoring action, and deny that notice to the putative Class need be provided.

PRAYER FOR RELIEF

84. Defendants deny that Plaintiffs are entitled to any relief, including any relief requested in the Prayer for Relief. Defendants deny any remaining allegations in the Prayer for Relief, including all its lettered parts.

DEFENSES AND AFFIRMATIVE DEFENSES

85. The First Amended Class Action Complaint fails to state a claim upon which relief can be granted.

86. Defendants incorporate by reference their Motions to Dismiss.

87. Plaintiffs' claims, and those of the purported class, are barred because this action is not properly maintainable as a class action as alleged by Plaintiffs.

88. The scope of the purposed class as alleged is vague and uncertain, and thus the class is not ascertainable. As such, this action is not properly maintainable as a class action.

89. Plaintiffs cannot meet the requirements of Rule 23 of the Federal Rules of Civil Procedure and corresponding case law to maintain a class action in that the purported class does not have sufficient numerosity, common issues of law and fact do not sufficiently predominate, the purported class does not have sufficient commonality of injuries and damages, the named Plaintiffs do not adequately represent the purported class, there is no benefit to litigants and the court in bringing this action as a class action, and the class action status is not superior to bringing this action in the normal course of the judicial system.

90. Plaintiffs' claims, and those of the purported class, are barred, in whole or in part, because Plaintiffs are not proper class representatives.

91. Plaintiffs cannot meet the requirements of Rule 23(b)(2) and corresponding case law to maintain a class action in that the purported class lacks cohesion among class members such that injunctive or declaratory relief is not appropriate as to the class as a whole.

92. Plaintiffs and purported class members cannot meet the requirements of medical monitoring, as recognized in Pennsylvania, in that Plaintiffs and purported class members cannot establish that they had exposure greater than normal background levels to a proven hazardous substance, caused by Defendants' negligence, that as a proximate result of the exposure, they have a significantly increased risk of contracting a serious latent disease, that a monitoring procedure exists that makes the early detection of the disease possible, and that any such monitoring regime is different than that normally recommended in the absence of any alleged exposure or reasonably necessary according to contemporary scientific principles.

93. Plaintiffs' and purported class members' request for declaratory relief should be dismissed for lack of standing.

94. Plaintiffs' recovery, and that of the purported class, is barred because the product at issue was in conformity with the generally recognized state of the art at the time it was designed, manufactured, packaged, labeled, distributed, and sold.

95. Plaintiffs' claims, and those of the purported class, are barred due to modification or alteration of the product by a person other than the Defendants.

96. Plaintiffs' claims, and those of the purported class, are barred due to use of the product for a purpose, in a manner, or in an activity other than that which was intended, including without limitation a use contrary to instructions and/or warnings applicable to the product.

97. Any amount that Plaintiffs or the purported class claim as compensatory damages or monitoring funds, if the claim for such amount is not entirely barred, must be diminished proportionately by the fault of others who caused or contributed to cause the harm.

98. Plaintiffs' claims, and those of the purported class, may be barred by the express or implied assumption of risk.

99. Plaintiffs' claims, and those of the purported class, may be barred, in whole or in part, due to actions or inactions of third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening, and superseding causes of the alleged exposures.

100. Plaintiffs and the purported class cannot recover under the FAC because the product at issue complied with all applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by

the United States; the individual States having applicable authority, if any; or by an agency of the United States or the above-named states.

101. Plaintiffs' claims, and those of the purported class, are barred by virtue of the intervention of a learned intermediary or intermediaries to whom the Defendants discharged their duty to warn.

102. The product at issue is a prescription medical device that is reasonably safe because reasonable health care providers prescribe the device for a class of patients, knowing the device's foreseeable risks and therapeutic benefits. Plaintiffs' claims, and those of the purported class, are barred or limited because the product is a prescription medical device and falls within the ambit of Restatement (Second) of Torts section 402A, Comment k.

103. Plaintiffs' claims, and those of the purported class, are barred, in whole or in part, by the doctrine of federal preemption.

104. Plaintiffs' claims, and those of the purported class, are barred, in whole or in part, because the Defendants did not breach any duty owed.

105. Any condition of the product in question alleged to be defective or to have constituted a breach of duty by the Defendants was not a proximate cause of Plaintiffs' or purported class members' alleged exposures or risk.

106. The product alleged by Plaintiffs and the purported class to have been defective complied with any and all relevant design and manufacture specifications.

107. The product alleged by Plaintiffs and the purported class to have been defective did not deviate from the design specifications, formulae or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae.

108. The Defendants aver that they did not know, and in light of the existing reasonably available scientific and technological knowledge, could not have known of (a) the design characteristics, if any, that allegedly caused the exposures and risk complained of herein or the alleged danger of such characteristics, or (b) any alternative design referred to by Plaintiffs or the purported class members. The Defendants further aver that any alternative design was neither feasible, either scientifically or technologically, nor economically practical.

109. Plaintiffs' claims, and those of the purported class, are barred because the FAC does not allege nor can Plaintiffs or the purported class prove that the product was too unsafe to be prescribed for or used by any patient.

110. Some purported class members' claims may be barred by the applicable statutes of limitations and/or statute of repose.

111. Plaintiffs' claims, and those of the purported class, may be barred due to the spoliation of evidence.

112. Plaintiffs' claims, and those of the purported class, may be barred by the equitable doctrines of laches, waiver, and estoppel.

113. The Defendants expressly preserve and do not knowingly or intentionally waive any of the other affirmative defenses, which discovery may reveal to be applicable, or any other matter constituting an avoidance or affirmative defense.

JURY TRIAL DEMANDED

Sorin Deutschland and Sorin USA hereby demand a trial by jury on all claims set forth in the FAC.

WHEREFORE, Defendants Sorin Deutschland and Sorin USA request that judgment be entered in their favor, with costs and fees as permitted by law, and against Plaintiffs with respect to the claims asserted in this suit, and for any other relief to which Sorin Deutschland and Sorin USA have shown themselves justly entitled.

Dated: October 25, 2016

Respectfully submitted,

s/Mark E. Gebauer
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CERTIFICATE OF SERVICE

I certify that on this 25th day of October 2016, I served a copy of **Defendants' Answer and Defenses to Plaintiffs' First Amended Class Action Complaint** via electronic filing addressed to the following:

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