IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PAMELA PAWLIK, an individual	)	
	)	
Plaintiff,	)	
	)	
vs.	)	No. 13-cv-1585
	)	
COCHLEAR LIMITED, an Australian public company and COCHLEAR AMERICAS CORPORATION, a Delaware corporation,	)	
	)	**JURY TRIAL DEMANDED**
Defendants.	)	

FIRST AMENDED COMPLAINT

Plaintiff, Pamela Pawlik, an individual, complaining against Defendants, Cochlear Limited, an Australian public company, and Cochlear Americas Corporation, a Delaware corporation, states as follows:

Nature of Action

1. Plaintiff, Pamela Pawlik ("Plaintiff"), brings this action because a Cochlear Nucleus CI512 cochlear implant medical device manufactured, distributed, and sold by Defendants Cochlear Limited and Cochlear Americas Corporation (the "Cochlear Implant") failed after it was surgically implanted into her body, requiring further surgery in an attempt to restore some part of Plaintiff's hearing.

2. The Cochlear Nucleus CI500 range of cochlear implant medical devices, which includes the Cochlear Nucleus CI512 model that Plaintiff received,

were subject to a global recall issued in September 2011, due to an increase in the number of Cochlear Nucleus CI512 implant failures.

3. The United States Food and Drug Administration ("FDA") had previously approved a certain design, materials, construction, manufacturing method, testing, and labeling of Defendants' Cochlear Nucleus CI512 cochlear implant medical device pursuant to that agency's premarket approval process ("PMA").

4. Specifically, Defendants' Cochlear Nucleus CI512 cochlear implant medical device was approved as a supplement to PMA P970051, which was originally approved by the FDA on or about June 25, 1998. The PMA supplement for Defendants' Cochlear Nucleus CI512 was approved by the FDA on August 28, 2009.

5. As is more fully set forth herein, Defendants failed to comply with the specifications and requirements of the PMA, federal law and federal regulations. As a result, Plaintiff suffered personal injuries.

6. As a result of Defendants' failure to comply with the specifications and requirements of the PMA, federal law and federal regulations, the Cochlear Nucleus CI500 range of cochlear implant medical devices, including the Cochlear Nucleus CI512, were subject to a global recall issued in September 2011.

7. This recall was predicated upon the Defendants' knowledge that their Cochlear Nucleus CI512 series had experienced an increased failure rate as result of "hermeticity" or sealing compromises in the Cochlear Nucleus CI512 devices, and

that these failures were caused by inexcusable manufacturing defects resulting from Defendants' failure to comply with the specifications and requirements of the PMA, federal law and federal regulations. These same defects caused the failure of Plaintiff's Cochlear Implant.

8. As more fully set forth herein, Defendants exposed Plaintiff to the risk of medical device failure, corrective surgery and personal injury, among other things, as a result of Defendants' failure to comply with the specifications and requirements of the PMA, federal law and federal regulations.

9. Plaintiff's claims are premised entirely on Defendants' failure to comply with the PMA, federal law, and federal regulations, subjecting Defendants to liability for Plaintiff's parallel state law claims set forth herein.

10. Plaintiff's parallel state law claims set forth herein will not impose any requirement or standard relating to the safety or effectiveness of the Cochlear Nucleus CI512 cochlear implant medical device, or any other matter regulated by the FDA, that is different from, or in addition to, any requirement applicable to the Cochlear Nucleus CI512 cochlear implant medical device under the PMA, federal law, or federal regulations.

11. Plaintiff does not challenge the FDA's approval of the design, manufacturing process, or labeling of a premarket approved medical device in this action. Rather, by pursuing her parallel state law claims set forth herein, Plaintiff seeks to hold Defendants responsible for her injuries and damages proximately

caused by their failure to comply with the specifications and requirements of the PMA, federal law, and federal regulations with respect to the Cochlear Implant.

12. Plaintiff does not claim herein that the Cochlear Implant should have been designed, manufactured, tested, marketed, or labeled in a manner different from that approved by the FDA.

13. Rather, as more fully set forth herein, Plaintiff claims that, with respect to the Cochlear Implant, Defendants' failure to comply with the specifications and requirements of the PMA, federal law, and federal regulations proximately caused her to suffer injuries and damages of a personal and pecuniary nature.

14. As more fully set forth herein, the Cochlear Implant that Plaintiff received was not manufactured according to the specifications and requirements of the PMA, federal law, and federal regulations; and therefore was not the Class III medical device approved by the FDA.

Parties

15. Plaintiff is a United States citizen and citizen of the State of Indiana, domiciled in Chesterton, Porter County, Indiana.

16. Defendant Cochlear Limited ("Cochlear") is an Australian public company with its principal place of business in New South Wales, Australia.

17. Cochlear holds itself out as "The leading global expert in implantable hearing solutions."

18. Defendant Cochlear Americas Corporation ("CAM") is a Delaware corporation with its principal place of business in Centennial, Colorado.

19. CAM is a wholly owned subsidiary of Cochlear.

20. Cochlear established and maintains CAM as its wholly owned subsidiary for the purpose of conducting business on behalf of and for the benefit of Cochlear in the United States, including in the forum state of Illinois.

21. Cochlear established and maintains CAM to create, control, and employ the distribution system that bring Cochlear's products into the United States, including the Cochlear Implant into the forum state of Illinois.

22. At all times relevant, Cochlear, through its directors, officers, employees, and agents, had actual knowledge that products that it manufactured, including the Cochlear Implant, were being marketed and sold in the forum state of Illinois.

23. At all times relevant herein, CAM's actions in the United States, including in the forum state of Illinois, on behalf of and for the benefit of Cochlear, include sales, marketing, distribution, service, finance, regulatory and administration of Cochlear's products, including the Cochlear Implant.

24. At all times relevant, the products that Cochlear manufactures, including the Cochlear Implant, have been sold and distributed exclusively in the United States through CAM.

25. At all times relevant, CAM has only sold, marketed, distributed, serviced, and sought regulatory approval for products manufactured by its parent corporation, Cochlear.

26. In furtherance of selling its Class III medical devices, including the Cochlear Implant, in the United States generally, and the forum state of Illinois, specifically, Cochlear obtained federal regulatory approval from the FDA.

27. At all times relevant, CAM's president has been Chris Smith.

28. Cochlear's Annual Reports covering the period when Plaintiff was implanted and explanted with the Cochlear Implant, described Mr. Smith's duties to Cochlear as follows: "Chris is responsible for the development and execution of the strategic direction for our operations in the Americas region, comprising North America, Central America and South America. Operations in the Americas include sales, marketing, distribution, service, finance, regulatory and administration across this fast growing region."

29. At all times relevant, CAM's president, Mr. Smith, reported directly to his immediate superior, Dr. Chris Roberts, the CEO and president of Cochlear.

30. Cochlear's fiscal year ending June 30, 2012 revenue for its "Americas" business region managed for Cochlear by CAM's president, Mr. Smith, was $297,000,000 Australian dollars, which was more than the fiscal year 2012 revenues for each of Cochlear's two other business regions, "Europe/Middle East/Africa" and "Asia Pacific."

31. At all times relevant, CAM's sales revenue for Cochlear's products in the United States, including Illinois, have been included in Cochlear's revenue figures reported in its Annual Reports.

32. At all times relevant, CAM's employees have been included in Cochlear's reporting of its total number of employees in its Annual Reports.

33. At all times relevant, Cochlear obtained and maintained at least six different U.S. trademark registrations from the United States Patent and Trademark Office for the mark "Cochlear" in various forms and classifications.

34. At all times relevant, CAM has maintained no trademark registrations from the United States Patent and Trademark Office for the mark "Cochlear" in any form, as all such U.S. trademarks are held by its parent corporation, Cochlear.

35. At all times relevant, Cochlear has owned more than 200 patents issued by the United States Patent and Trademark Office related to the products that it manufactures, including the Cochlear Implant, and/or their component parts.

36. At all times relevant, CAM has owned no patents issued by the United States Patent and Trademark Office related to any of the products that it sells, or their component parts, as all such patents are held by its parent corporation, Cochlear.

37. At all times relevant, Cochlear directed CAM with respect to obtaining FDA regulatory approval to sell numerous Cochlear-manufactured Class III medical devices in the United States, including the Cochlear Implant sold and delivered to Plaintiff in Illinois.

38. At all times relevant, CAM has acted at the specific direction of its parent corporation, Cochlear, with respect to obtaining FDA regulatory approval to sell numerous Cochlear-manufactured Class III medical devices in the United States, including the Cochlear Implant sold and delivered to Plaintiff in Illinois.

39. At all times relevant, Cochlear directed CAM to advertise, market, and sell its Cochlear Nucleus CI512 medical devices, including Plaintiff's Cochlear Implant, to medical providers and consumers in Illinois, including to Plaintiff's surgeon and Plaintiff.

40. At all times relevant, at Cochlear's direction, CAM advertised, marketed, and sold Cochlear Nucleus CI512 medical devices, including Plaintiff's Cochlear Implant, to medical providers and consumers in the forum state of Illinois, including Plaintiff's cochlear implant surgeon and Plaintiff.

41. At all times relevant, Cochlear targeted medical providers and consumers in Illinois for the sale of Cochlear Nucleus CI512 medical devices, including Plaintiff's Cochlear Implant.

42. At all times relevant, at Cochlear's direction, CAM targeted medical providers and consumers in Illinois for the sale of Cochlear Nucleus CI512 medical devices, including Plaintiff's Cochlear Implant.

43. At all times relevant, Cochlear has advertised on its principal website, www.cochlear.com, the "Cochlear Awareness Network Events" that Defendants regularly sponsor and host in multiple locations in the Northern District of Illinois, including the Chicago Marriott Schaumburg, where consumers like Plaintiff can

"Explore how the Cochlear® Awareness Network can be a resource for those seeking information on advanced hearing loss solutions and provide support to those who have Nucleus® Cochlear Implant and Baha® technology!"

44. At all times relevant, CAM has advertised, sponsored, and hosted "Cochlear Americas Hearing Health Seminars" in multiple locations in the Northern District of Illinois, including the Chicago Marriott Schaumburg, where consumers like Plaintiff can attend a "free educational event" to "attend hearing loss education sessions and ask questions," as well as "meet cochlear implant users, doctors and audiologists," and "learn how cochlear implants are covered by Medicare, most insurance plans, and may be covered by Medicaid."

45. Through Cochlear's website www.cochlearcommunity.com, Cochlear sponsors the "Illinois Cochlear Group" which it describes as being "For those of us who live anywhere in Illinois" and, among other things, shows pictures at www.cochlearcommunity.com/canil/weblog/22329.html of a Cochlear sponsored and branded canopy tent that was-- according to the narrative accompanying the pictures-- located in Chicago, Illinois on October 6, 2013 at a charity walk, where "Cochlear Volunteers and Colleagues" "…had an opportunity to share the 'new' Nucleus 6 demo kit with the walk attendees."

46. At all times relevant Defendants, both individually and collectively, were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, obtaining regulatory approval for, and introducing into the stream of commerce throughout the United States, including the forum state of

Illinois, numerous products manufactured by Cochlear, including Plaintiff's Cochlear Implant.

47. As a result of all of the foregoing, Defendants sold and delivered the Cochlear Implant in the forum state of Illinois.

48. As a result of all of the foregoing, Defendants' sale and delivery of the Cochlear Implant in the forum state of Illinois was not simply an isolated occurrence, but rather arose from Defendants' efforts to create and serve the market for their products, including the Cochlear Implant, in the forum state of Illinois.

49. As a result of all of the foregoing, the Cochlear Implant was surgically implanted into Plaintiff in DuPage County, Illinois.

50. In connection with the sale and implantation of the Cochlear Implant, Defendants delivered an express ten year written warranty to Plaintiff warranting to Plaintiff that the Cochlear Implant was a safe and effective hearing device that had been manufactured in accordance with the PMA, CGMP, federal law and federal regulations.

51. Defendants expressly warranted to Plaintiff that the Cochlear Implant was of merchantable quality, reasonably fit for the purpose or purposes for which it was supplied by Defendants, and free from defects in design, workmanship, and materials for the ten year warranty period.

52. The warranty advises Plaintiff that she could contact "… Cochlear at one of the customer service addresses nearest to you listed below" and then lists "Customer Service: Cochlear Americas" at Defendant CAM's principal office address

in Centennial, Colorado, along with Defendant CAM's telephone number and an email of customer@cochlear.com.

53. The warranty identifies the location of CAM's principal office as one of Cochlear's "customer service addresses."

Jurisdiction and Venue

54. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332(a) because there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy, exclusive of interest and costs, exceeds $75,000.

55. Venue is proper in this district pursuant to 28 U.S.C. §1391(b)(2), because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this district, including Plaintiff's receipt of and implantation with the Cochlear Implant in Hinsdale, DuPage County, Illinois.

56. Defendants are subject to personal jurisdiction in this district pursuant to 735 ILCS 5/2-209, because Plaintiff's claims arise from Defendants' actions in transacting business in the State of Illinois, and Defendants' commission of a tortious act in the State of Illinois.

57. Defendant Cochlear's actions, by which it both purposefully availed itself to the forum state of Illinois and delivered Class III medical devices, including the Cochlear Implant, into a stream of commerce that Cochlear itself created with the knowledge and expectation that the medical devices it manufactured would be

purchased by and surgically implanted into consumers in Illinois, such as Plaintiff, include:

a. Establishing CAM as its wholly owned U.S. subsidiary to perform sales, marketing, distribution, service, finance, regulatory and administration of Cochlear's products, including the Cochlear Implant, in the United States, including the forum state of Illinois, for the exclusive benefit of Cochlear;

b. Carrying on purposeful business activity in Illinois through its wholly owned subsidiary, CAM, which only markets and sells Cochlear manufactured products, by such actions as having Plaintiff's hospital and Plaintiff as customers for its Class III medical devices, including the Cochlear Implant;

c. Having actual knowledge that the products that it manufactured, including the Cochlear Implant, were being marketed and sold in the forum state of Illinois;

d. Targeting the forum state of Illinois by soliciting business in Illinois through its wholly owned subsidiary, CAM, as well as through its own Cochlear website reasonably designed to reach consumers such as Plaintiff;

e. Marketing its products, including the Cochlear Implant, to consumers, including Plaintiff, using Cochlear's trademarks registered with the U.S. Patent and Trademark Office;

f. Protecting its intellectual property rights in its products marketed and sold in the United States, including Illinois, through the more than 200 patents issued to Cochlear by the U.S. Patent and Trademark Office;

g. Performing testing services in Illinois on Cochlear manufactured Class III medical devices, including the Cochlear Implant, through employees or agents of Defendants.

58. Defendants are subject to personal jurisdiction in this district in accordance with Illinois' long-arm statute and federal constitutional requirements because they have both purposefully availed themselves of the forum state of

Illinois' benefits, and Plaintiff's claims complained of herein arise out of and/or relate to both Defendants' transaction of business within the State of Illinois, and Defendants' commission of a tortious act within the State of Illinois.

FACTUAL BACKGROUND

Cochlear Implants

59. Cochlear implants are surgically implanted medical devices that provide a sense of sound to people who are either profoundly deaf or severely hard of hearing.

60. The Cochlear Implant is intended to convert sound into electrical energy that activates the auditory nerve, which then sends the information to the brain, where it is interpreted as sound.

61. Plaintiff's Cochlear Implant is part of a system that contains both internal and external components.

62. Plaintiff's Cochlear Implant's system's external components include a sound processor and magnetic coil that are worn behind the ear.

63. Plaintiff's Cochlear Implant's system's internal (surgically implanted) components include a receiver/stimulator that is housed in what is designed as and intended to be a hermetically sealed (i.e. moisture impervious) titanium chassis; a platinum receiver coil; and an intra-cochlear electrode array. The internal components are surgically implanted behind the ear, and into the cochlea (inner ear).

64. Plaintiff's Cochlear Implant's internal receiver/stimulator contains a feedthrough assembly that provides the connection between the electrical circuitry contained in the Cochlear Implant's intended-to-be hermetically sealed (i.e. moisture impervious) titanium chassis, and the Cochlear Implant's intra-cochlear electrode array.

65. The FDA approved a certain design, materials, construction, manufacturing method, testing, and labeling of Defendants' Cochlear Nucleus CI512 cochlear implant medical device pursuant to that agency's premarket approval process ("PMA").

66. The CI512 model cochlear implant was approved as supplement S048 to PMA P970051, which PMA was originally approved by the FDA on or about June 25, 1998. The FDA approved PMA supplement S048 for the CI512 model cochlear implant on August 28, 2009.

67. Once a device has received PMA, the Medical Device Amendments of 1976 ("MDA"), 21 U. S. C. §360c *et seq.*, forbid the manufacturer from making, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness.

68. Once the FDA approves a medical device, any information that reasonably suggests that the device (1) "[m]ay have caused or contributed to a death or serious injury" or (2) "[h]as malfunctioned" and that any recurring malfunction "would be likely to cause or contribute to a death or serious injury" must be reported to the FDA. 21 C.F.R. § 803.50(a); see 21 U.S.C. § 360i(a).

69. As is more fully set forth herein, with respect to Plaintiff's Cochlear Implant, Defendants failed to comply with the specifications and requirements of the PMA, federal law and federal regulations. As a proximate result thereof, Plaintiff suffered injuries and damages of a personal and pecuniary nature.

The Cochlear Nucleus CI500 Range Failure and Recall

70. On or about September 13, 2011, the Australian government issued an urgent medical device recall and hazard alert in connection with unimplanted Cochlear Nucleus CI500 range of cochlear implant medical devices, which included the Cochlear Nucleus CI512 model (the model of Plaintiff's Cochlear Implant).

71. The stated reason for the Australian governmental recall was that it followed a recent increase in the number of failures of Cochlear Nucleus CI512 model cochlear implants. The recall was considered a safety related recall.

72. In September 2011 Defendant CAM sent an "URGENT MEDICAL DEVICE RECALL" letter to its affected customers. The letter described the product, the problem, and actions to be taken by the customers. The letter instructed customers to examine their inventory and quarantine the affected product.

73. On or about October 3, 2011 the FDA issued a Class 2 Recall, pursuant to Recall Number Z-0003-2012, for unimplanted Cochlear Nucleus CI512 model cochlear implants.

74. According to the FDA's October 3, 2011 recall, the reason for the recall was that the recalled devices may shut down and cease to function.

75. According to the FDA, there was worldwide distribution of the recalled devices, including nationwide distribution in the United States.

76. On or about December 16, 2011, Defendant Cochlear publicly released a letter from its CEO and president, Dr. Chris Roberts, stating:

> "This letter updates progress on investigations associated with the voluntary recall of unimplanted Nucleus CI500 series implants, specifically information on the root cause of the loss of hermeticity.
>
> **The results of our investigation to date point to a loss of hermeticity from unexpected variations in the brazing process during manufacturing. Brazing is the process that joins the feedthrough to the titanium chassis. Variations in the brazing process have resulted in a limited number of implants being more susceptible to developing microcracks in the braze joint during subsequent manufacturing steps. These microcracks allow water molecules to enter the implant resulting in the malfunction of specific electronic components (typically one of four diodes).**
>
> ***
>
> The overall proportion of CI500 series devices that has failed is approximately 1.9% of registered implants globally with similar percentages in all three regions (The Americas, Europe Middle East & Africa (EMEA) and Asia Pacific). There were fewer reported failures in November 2011 than in October 2011." (Emphasis added).
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> ***

77. On or about February 6, 2012 Defendant Cochlear publicly released another letter from its CEO and president, Dr. Chris Roberts, advising, among other things, that:

> "This letter provides the latest information regarding the voluntary recall of unimplanted Nucleus CI500 series implants, specifically information regarding the latest observations associated with the number of reported devices failing, the failure mechanism and the clinical symptoms associated with the failure mechanism.
>
> **In December 2011, we reported the root cause for the loss of hermeticity to be unexpected variations in the brazing**

> **process that joins the feedthrough to the titanium chassis during manufacturing. These variations resulted in a limited number of implants being more susceptible to developing microcracks in the braze joint during subsequent manufacturing steps.** These microcracks allow water molecules to enter the implant resulting in the malfunction of specific electronic components (typically one of four diodes). Failure of these electronic components results in the implant shutting down. This failure mechanism continues to be consistent with no other failure mechanism associated with the loss of hermeticity identified.
>
> As of January 31st, 2012, the overall proportion of Nucleus CI500 series devices that has been reported as failed is 2.4% of registered devices globally…" (Emphasis added).

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Facts Regarding Plaintiff

78. Plaintiff has, at all times relevant herein, suffered from profound hearing loss.

79. Plaintiff was medically evaluated for a cochlear implant medical device, and determined to be an excellent candidate to receive a cochlear implant medical device.

80. On or about May 4, 2011, a Cochlear Nucleus CI512 cochlear implant medical device designed, manufactured, distributed, and placed in the stream of commerce by Defendants, was surgically implanted into Plaintiff's body at Adventist Hinsdale Hospital, in Hinsdale, DuPage County, Illinois.

81. In or about August of 2011, Plaintiff's Cochlear Implant failed, and this was the first date that Plaintiff could have known that the Cochlear Implant had failed

82. Plaintiff's Cochlear Implant failed due to an electronic failure caused by a loss of hermeticity (i.e. failure of the moisture impervious seal) of the titanium chassis of the Cochlear Implant's internal receiver/stimulator.

83. This loss of hermeticity in Plaintiff's Cochlear Implant's internal receiver/stimulator was the result of unintended variations in the brazing process that occurred during Defendants' manufacture of Plaintiff's Cochlear Implant.

84. Brazing is the process that joined the feedthrough of Plaintiff's Cochlear Implant to its titanium chassis.

85. These unintended variations in the brazing process during the manufacture of Plaintiff's Cochlear Implant resulted in Plaintiff's Cochlear Implant being more susceptible to developing microcracks in its braze joint during subsequent manufacturing processes.

86. Microcracks developed in the braze joint of Plaintiff's Cochlear Implant during the manufacturing process.

87. Microcracks in the braze joint of Plaintiff's Cochlear Implant allowed water molecules to enter Plaintiff's Cochlear Implant and cause the malfunction and eventual failure of the Cochlear Implant's electronic components.

88. Defendants thereafter failed to detect the microcracks in Plaintiff's Cochlear Implant's braze joint during its manufacturing process and related testing.

89. The microcracks in Plaintiff's Cochlear Implant's braze joint existed at the time that Plaintiff's Cochlear Implant left the hands of Defendants.

90. On or about August 31, 2011, at Adventist Hinsdale Hospital, in Hinsdale, DuPage County, Illinois, the Cochlear Implant was surgically explanted from Plaintiff's body due to the failure of the Cochlear Implant's electronic components as a result of the Cochlear Implant's loss of hermeticity.

91. Defendant Cochlear received the explanted Cochlear Implant on or about September 12, 2011, and thereafter conducted a post-failure analysis of the explanted Cochlear Implant.

92. Defendant Cochlear's own post-failure analysis of the explanted Cochlear Implant determined that the Cochlear Implant failed due to an electronic failure caused by a loss of hermeticity (i.e. failure of the moisture impervious seal) of the titanium chassis of the Cochlear Implant's internal receiver/stimulator.

93. Specifically, Defendant Cochlear's own "Analysis of Returned Device" report concerning Plaintiff's Cochlear Implant provides that the outcome of Defendant Cochlear's investigation was that "The device was explanted due to loss of function. Analysis found a malfunctioning electronic component (capacitor) on the PCB and a hermetic seal failure. The conclusion from device analysis is that the loss of function was caused by moisture penetrating the hermetic seal and impacting the diode function."

Federal Requirements

94. The Cochlear Implant is a Class III medical device regulated by the United States Food and Drug Administration ("FDA").

95. The FDA requires a device that has received premarket approval, such as the Cochlear Implant, to be made with no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.

96. Specifically, 21 C.F.R.§ 814.80 provides that "[a] device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."

97. A medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. § 351.

98. Medical device manufacturers such as Defendants are required to comply with FDA regulation of medical devices in order to prohibit the introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices.

99. In addition to the conditions to approval specified in the PMA approval order for the medical device, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device

conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. 21 U.S.C. § 360j(f).

100. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR § 820 et seq.

101. Pursuant to 21 CFR § 820.1(c), the failure to comply with the provisions in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351).

102. Pursuant to 21 CFR § 820.30(g), each manufacturer of a medical device, such as Defendants, shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. 21 CFR § 820.30(g) (Emphasis added).

103. On Plaintiff's information and belief, at all times relevant Defendants failed to perform the mandated design validation by testing production units of the Cochlear Nucleus CI512 under actual or simulated use conditions, in violation of 21 CFR § 820.30(g).

104. Prior to the date that Plaintiff was implanted with the Cochlear Implant, Defendants had received information that reasonably suggested that the Cochlear Nucleus CI512 "[m]ay have caused or contributed to a serious injury" or

"malfunctioned" and that any recurring malfunction would be likely to cause or contribute to a death or serious injury, but failed to report this information to the FDA pursuant to 21 C.F.R. § 803.50(a) and 21 U.S.C. § 360i(a).

105. Plaintiff's Cochlear Implant experienced an unintended loss of hermeticity.

106. This loss of hermeticity was the result of unintended variations in the brazing process during Defendants' manufacture of Plaintiff's Cochlear Implant, and such unintended variations in the brazing process were contrary to the requirements of the PMA, federal law, and federal regulations.

107. Brazing is the metal-joining manufacturing process that joined the feedthrough of Plaintiff's Cochlear Implant to the receiver/stimulator's titanium chassis.

108. Unintended variations in the brazing process during Defendants' manufacture of Plaintiff's Cochlear Implant that were contrary to the requirements of the PMA, federal law, and federal regulations, resulted in Plaintiff's Cochlear Implant being more susceptible to developing microcracks in its braze joint during Defendants' subsequent manufacturing steps.

109. As a result of these unintended variations in the brazing process during Defendants' manufacture of Plaintiff's Cochlear Implant, microcracks developed in Plaintiff's Cochlear Implant's braze joint during its manufacturing process, which process was contrary to the requirements of the PMA, federal law, and federal regulations.

110. Defendants failed to detect these microcracks in the braze joint of Plaintiff's Cochlear Implant during the manufacturing process, or after the manufacturing process but before the Cochlear Implant left Defendants' control, contrary to the requirements of the PMA, federal law, and federal regulations.

111. These microcracks in the braze joint of Plaintiff's Cochlear Implant existed at the time that Plaintiff's Cochlear Implant left the control of Defendants for sale, contrary to the requirements of the PMA, federal law, and federal regulations.

112. As a result of the microcracks that existed in the braze joint of Plaintiff's Cochlear Implant at the time that Plaintiff's Cochlear Implant left the control of Defendants for sale, Plaintiff's Cochlear Implant was adulterated pursuant to 21 U.S.C. § 351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation was not in conformity with federal requirements. See 21 U.S.C. § 351.

113. As a result of the microcracks that existed in the braze joint of Plaintiff's Cochlear Implant at the time that Plaintiff's Cochlear Implant left the control of Defendants, Plaintiff's Cochlear Implant was misbranded because, among other things, it was dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352.

114. Plaintiff's Cochlear Implant was adulterated pursuant to 21 U.S.C. § 351 because Defendants failed, among other things, to establish and maintain

CGMP for Plaintiff's Cochlear Implant in accordance with 21 CFR § 820 et seq., as set forth above, by failing to perform the mandated design validation by testing production units of the Cochlear Nucleus CI512 under actual or simulated use conditions, in violation of 21 CFR § 820.30(g). As a result of Defendants' failure to establish and maintain CGMP as set forth above, Plaintiff's Cochlear Implant was adulterated, defective, and failed, resulting in injuries to Plaintiff.

115. If Defendants had complied with the federal requirements regarding CGMP in the manufacture of Plaintiff's Cochlear Implant, then Plaintiff's Cochlear Implant would have undergone manufacturing related testing in accordance with the PMA that would have revealed the microcracks that existed in the braze joint of Plaintiff's Cochlear Implant at the time that Plaintiff's Cochlear Implant left the hands of Defendants for sale, such that the defective Cochlear Implant would not have been implanted in Plaintiff's body.

116. Additionally, during the manufacture of Plaintiff's Cochlear Implant, Defendants' unintended variations in the brazing process, and the microcracks that existed in the braze joint of Plaintiff's Cochlear Implant as a result thereof, deviated from the conditions of approval specified in the PMA order for the Cochlear Implant, and violated the PMA, CGMP, federal law and federal regulations because Defendants:

(a) Failed to comply with MIL-STD-883 Test Method 1014 in the manufacture of the Cochlear Implant, by performing the "bubble test" before the "fine leak" test;

(b) Failed to comply with MIL-STD-883 Test Method 2009 and/or JEDEC Standard 9 in the manufacture of the Cochlear Implant;

(c) Failed to comply with MIL-STD-883 Test Method 1018, by failing to properly set calibrations in the equipment necessary for the proper functioning of the equipment;

(d) Failed to qualify the Cochlear Implant using a hydrostatic pressure test and a corrosion test known, respectively, as QTP1190 and QTR1190;

(e) Failed to perform the QTP1190 or the QTR1190 tests as required or in the alternative, performed these tests improperly on the Cochlear Implant;

(f) Failed to comply with the specified hermetic seal test procedures during the Cochlear Implant's manufacture;

(g) Failed to perform the required visual inspections of the Cochlear Implant, and therefore failed to visualize the microcracks that existed in the Cochlear Implant's braze joint;

(h) Failed to follow the criteria for rejecting the Cochlear Implant as a result of the presence of microcracks in the Cochlear Implant's braze joint;

(i) Failed to utilize the equipment, including the correct microscopic equipment, specified in the PMA necessary to observe the presence of microcracks in the Cochlear Implant's braze joint;

(j) Failed to use alloy material in the Cochlear Implant's braze joint that was in compliance with specifications;

(k) Failed to follow the process set forth in the PMA for the detection of alloy material that was not in compliance with the specifications, prior to using the non-compliant alloy material in the Cochlear Implant's manufacturing process;

(l) Employed a laser, resistance welder, or oven in the Cochlear Implant's manufacturing process that failed to conform to specifications;

(m) Failed to control the environmental conditions inside the oven employed in the Cochlear Implant's manufacturing process by failing to utilize temperatures specified;

(n) Failed to inspect and control the hermetic sealing equipment used in the manufacture of the Cochlear Implant, including environmental

control systems such as the laser and/or the manufacturing oven, to verify that such equipment and systems functioned as required;

(o) Failed to utilize the manufacturing oven under the atmospheric conditions specified for the manufacture of the Cochlear Implant;

(p) Failed to employ procedures in the manufacture of the Cochlear Implant to prevent contamination of the braze joint, as specified;

(q) Failed to maintain procedures in the manufacture of the Cochlear Implant for the identification and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the quality of the Cochlear Implant, as required;

(r) Failed to establish and maintain procedures in the manufacturing process to control cochlear implants, including Plaintiff's Cochlear Implant, that fail to conform to specified requirements;

(s) Failed to develop, conduct, control, and monitor its production processes as required to ensure that the Cochlear Implant conformed to specifications;

(t) Misbranded the Cochlear Implant by concealing known risks, in violation of 21 C.F.R. §§803.50(a)(1) and 806.10(a)(1);

(u) Failed to perform design validation testing including accelerated life cycle testing in an environment mimicking the human implant environment, in violation of 21 CFR 820.30(g);

(v) Failed to validate the entire device, not just component parts, as required;

(w) Failed to execute properly on the manufacturing floor by failing to execute pursuant to the FDA baseline set of documents in the PMA relating to manufacturing processes necessary to prevent microcracks in the Cochlear Implant's braze joint;

(x) Violated specific CGMP in the manufacture of the Cochlear Implant, including the failure to conduct management reviews with sufficient frequency, failure to establish required auditing, training, operating, testing, and quality assurance procedures including supplier quality procedures and audits;

(y) Failed to conduct adequate post-marketing surveillance of the Cochlear Nucleus CI512, as required;

(z) Failed to notify and warn the public, including Plaintiff or her physician, of reported incidents of failure, necessitating surgery, personal injury attendant to the failure, thus misrepresenting the safety of the Cochlear Implant;

(aa) Failed to use due care in the testing, formulation, inspection, distribution, sale and instructions regarding the Cochlear Nucleus CI512 at all times prior to Plaintiff's injuries having manifested themselves, as required;

(bb) Continued to promote and market the Cochlear Nucleus CI512 despite their knowledge of these risks at the time that Plaintiff was implanted with the Cochlear Implant;

(cc) Failed to inspect environmental control systems, including those in the manufacturing oven, to verify that the systems functioned pursuant requirements; and

(dd) Failed to report to the FDA information that Defendants received that reasonably suggested that the Cochlear Nucleus CI512 cochlear implants (1) "[m]ay have caused or contributed to a serious injury" or "malfunctioned" and that any recurring malfunction would be likely to cause or contribute to a death or serious injury but failed to report this information pursuant to 21 C.F.R. § 803.50(a) and 21 U.S.C. § 360i(a).

117. As a result of Defendants' deviations from the conditions of approval specified in the PMA order for the Cochlear Implant, as well as CGMP, federal law and federal regulations, as set forth above, Plaintiff's Cochlear Implant was adulterated, defective, and failed, resulting in injuries to Plaintiff.

FIRST CAUSE OF ACTION:
STRICT PRODUCTS LIABILITY- DEFECTIVE MANUFACTURING

118. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

119. Defendants designed and/or manufactured and/or distributed and/or sold and/or supplied and/or placed in the stream of commerce Plaintiff's Cochlear Implant.

120. Plaintiff's Cochlear Implant that Defendants designed and/or manufactured and/or distributed and/or sold and/or supplied and/or placed in the stream of commerce was defective in its manufacture, construction, or composition when it left the hands of Defendants in that Plaintiff's Cochlear Implant deviated in a material way from the PMA, CGMP, Defendants' approved product specifications, Defendants' approved manufacturing performance standards, and/or other applicable federal law and federal regulations applicable to Plaintiff's Cochlear Implant, as described above, posing a serious risk of medical device failure and associated medical treatment, including surgical procedures to remove the Cochlear Implant and replace it with a non-defective cochlear implant medical device. This conduct rendered the Cochlear Implant defective, adulterated, and more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

121. Plaintiff's Cochlear Implant that Defendants designed and/or manufactured and/or distributed and/or sold and/or supplied and/or placed in the stream of commerce was expected to and did reach Plaintiff without a substantial change in the condition in which it was sold.

122. As a direct and proximate result of Plaintiff's use of the Cochlear Implant designed and/or manufactured and/or distributed and/or sold and/or

supplied and/or placed in the stream of commerce by Defendants, and Defendants' failure to comply with the PMA, CGMP, Defendants' approved product specifications, Defendants' approved manufacturing performance standards, and/or other applicable federal law and federal regulations applicable to Plaintiff's Cochlear Implant, Plaintiff suffered serious physical injury, harm, damages, economic loss and will continue to suffer such harm, damages, and economic loss in the future.

123. Defendants' acts and/or omissions as alleged in this Complaint constitute an utter disregard for human safety, warranting the imposition of punitive damages.

SECOND CAUSE OF ACTION:
STRICT PRODUCTS LIABILITY- DESIGN DEFECT

124. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

125. Defendants are the designers and/or manufacturers and/or distributors and/or sellers and/or suppliers of Plaintiff's Cochlear Implant.

126. Plaintiff's Cochlear Implant, as manufactured and/or supplied by Defendants, was defective in design or formulation in that, when it left the hands of Defendants, the foreseeable risks of harm posed by Plaintiff's Cochlear Implant exceeded the benefits associated with the design or formulation, and Plaintiff's Cochlear Implant was more dangerous than an ordinary consumer would expect, because it failed to comply with federal requirements for such medical devices.

127. The foreseeable risks associated with the design or formulation of Plaintiff's Cochlear Implant, include, but are not limited to, the fact that the design or formulation of Plaintiff's Cochlear Implant is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

128. As a direct and proximate result of Plaintiff's use of the Cochlear Implant, as designed and/or manufactured and/or distributed and/or sold and/or supplied and/or placed in the stream of commerce by Defendants and Defendants' failure to comply with the PMA, CGMP, federal law and federal regulations, as described above, Plaintiff suffered serious physical injury, harm, damages, economic loss and will continue to suffer such harm, damages and economic loss in the future.

129. Defendants' acts and omissions as alleged in this Complaint demonstrate an utter disregard for human safety, warranting the imposition of punitive damages.

THIRD CAUSE OF ACTION:
STRICT PRODUCTS LIABILITY-
DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS

130. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

131. Defendants are the designers and/or manufacturers and/or distributors and/or sellers and/or suppliers of Plaintiff's Cochlear Implant.

132. Plaintiff's Cochlear Implant, as manufactured and supplied by Defendants, was defective in that, when it left the hands of Defendants, it did not

conform to representations made by Defendants concerning the product in that, as described above, it failed to comply with the PMA, CGMP, federal law or federal regulations.

133. Plaintiff and/or Plaintiff's physicians justifiably relied upon Defendants' representations regarding Plaintiff's Cochlear Implant when they selected Plaintiff's Cochlear Implant to be implanted on or about May 4, 2011.

134. As a direct and proximate result of Plaintiff's use of the Cochlear Implant, and Plaintiff's reliance on Defendants' representations regarding the character and quality of Plaintiff's Cochlear Implants and Defendants' failure to comply with the PMA, CGMP, federal law and federal regulations, as described above, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

135. Defendants' acts and omissions as alleged in this Complaint demonstrate an utter disregard for human safety, warranting the imposition of punitive damages.

FOURTH CAUSE OF ACTION:
FAILURE TO WARN

136. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

137. Defendants violated a state-law duty of care by failing to report known risks associated with the use of the Cochlear Implant to the FDA.

138. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her physician, of the true risks of Plaintiff's Cochlear

Implant, including the propensity to fail, causing pain and suffering and requiring further treatment, including surgery. Defendants failed to comply with their duty under federal law and breached their duty to use reasonable care under applicable state negligence law.

139. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of Plaintiff's Cochlear Implant.

140. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

141. As a direct and proximate result of the conduct of Defendants, as described above, Plaintiff suffered or will suffer serious and permanent non-economic and economic injuries.

142. Defendants' conduct, as described above, was reckless. Defendants risked the lives and health of consumers, including Plaintiff, based on the suppression of knowledge relating to the safety and efficacy problems with Plaintiff's Cochlear Nucleus model CI512. Defendants made a conscious decision not to notify the FDA as required by law, thereby putting increased profits over the public safety, including Plaintiff's safety. Defendants' actions and omissions as alleged in this Complaint demonstrate an utter disregard for human safety, warranting the imposition of punitive damages.

FIFTH CAUSE OF ACTION:
NEGLIGENCE

143. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

144. Defendants had a duty to exercise ordinary care in following the PMA, CGMP, federal law and federal regulations in the design, formulation, testing, quality assurance, quality control, labeling, manufacture, marketing, promotion, sale and/or distribution of Plaintiff's Cochlear Implant into the stream of commerce.

145. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of Plaintiff's Cochlear Implant into the stream of commerce in that Defendants knew or should have known that Plaintiff's Cochlear Implant had a propensity to fail and cause bodily harm and was not safe for use by consumers due to Defendants' failure to comply with the PMA, CGMP, federal law or federal regulations, as described above.

146. Defendants had a duty to exercise ordinary care in the advertising and sale of Plaintiff's Cochlear Implant, including a duty to warn Plaintiff or her physician of the dangers associated with the Cochlear Implant that were known or should have been known to Defendants at the time of sale to Plaintiff.

147. Defendants failed to exercise ordinary care in the advertising and sale of Plaintiff's Cochlear Implant by failing to warn Plaintiff or her physician of the dangers associated with the Cochlear Implant that were known or should have been known to Defendants at the time of sale to Plaintiff. Defendants failed to warn

Plaintiff or her physician that the Cochlear Implant had a propensity to fail, cause bodily harm and require surgical replacement due to Defendants' failure to follow the PMA, CGMP, federal law and federal regulations, as described above.

148. Defendants had a duty to exercise ordinary care in the labeling of the Cochlear Implant and failed to issue adequate pre-marketing or post-marketing warnings to physicians, Plaintiff or the general public, regarding the propensity of the Cochlear Implant to fail, cause bodily harm and require surgical replacement all due to Defendants' failure to follow the PMA, CGMP, federal law and federal regulations, as described above.

149. Despite the fact that Defendants knew or should have known that the Cochlear Implant posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Cochlear Nucleus CI512 for use by consumers, including Plaintiff, even though they failed to comply with the PMA, CGMP, federal law and federal regulations with respect to this medical device, as described above.

150. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

151. Defendants' conduct breached their duty of ordinary care to Plaintiff by failing to exercise ordinary care under the circumstances.

152. As a direct and proximate result of Defendants' acts and omissions, Plaintiff suffered serious physical injury, harm, damages and economic loss,

including but not limited to undergoing surgery, pain and suffering and will continue to suffer such harm, damages and economic loss in the future.

153. Defendants conduct as described herein was reckless. Defendants risked the life and health of Plaintiff through the sale of the Cochlear Implant to her with knowledge of the safety and efficacy problems and suppressed this knowledge from the FDA and the general public, including Plaintiff. Upon information and belief, Defendants made conscious decisions not to notify the FDA, or warn or inform the unsuspecting consuming public, including Plaintiff. Defendant placed profits before public safety. Defendants' actions and omissions as alleged in this Complaint demonstrate an utter disregard for human safety, warranting the imposition of punitive damages.

SIXTH CAUSE OF ACTION:
NEGLIGENCE PER SE

154. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

155. Defendants had a duty to exercise ordinary care in following the PMA, CGMP, federal law and federal regulations in the design, formulation, testing, quality assurance, quality control, labeling, manufacture, marketing, promotion, sale and/or distribution of Plaintiff's Cochlear Implant into the stream of commerce.

156. Defendants failed to exercise ordinary care in the design, formulation, testing, quality assurance, quality control, labeling, manufacture, marketing, promotion, sale and/or distribution of Plaintiff's Cochlear Implant into the stream of commerce in that Defendants knew or should have known that Plaintiff's Cochlear

Implant had a propensity to fail and cause bodily harm and was not safe for use by consumers, including Plaintiff, because Defendants failed to comply with the PMA, CGMP, federal law or federal regulations, as described above.

157. Despite the fact that Defendants knew or should have known that the Cochlear Implant posed a serious risk of bodily harm to consumers, including Plaintiff, Defendants continued to manufacture and market the Cochlear Nucleus CI512 for use by consumers, including Plaintiff, even though they failed to comply with the PMA, CGMP, federal law and federal regulations with respect to this medical device, as described above.

158. Plaintiff, as the recipient of the Cochlear Implant, is within the class of persons the statutes and regulations described above are designed to protect and Plaintiff's injuries complained of herein are the type of harm these statutes and regulations are designed to prevent.

159. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

160. Defendants' conduct breached their duty of ordinary care to Plaintiff by failing to exercise ordinary care under the circumstances.

161. As a direct and proximate result of Defendants' acts and omissions, Plaintiff suffered serious physical injury, harm, damages and economic loss, including but not limited to undergoing surgery, pain and suffering and will continue to suffer such harm, damages and economic loss in the future.

162. Defendants conduct as described herein was reckless. Defendants risked the life and health of Plaintiff through the sale of the Cochlear Implant to him with knowledge of the safety and efficacy problems and suppressed this knowledge from the FDA and the general public, including Plaintiff. Upon information and belief, Defendants made conscious decisions not to notify the FDA, or warn or inform the unsuspecting consuming public, including Plaintiff. Defendant placed profits before public safety. Defendants' actions and omissions as alleged in this Complaint demonstrate an utter disregard for human safety, warranting the imposition of punitive damages.

SEVENTH CAUSE OF ACTION:
BREACH OF EXPRESS WARRANTY

163. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

164. Defendants expressly warranted to Plaintiff that the Cochlear Implant was a safe and effective hearing device that had been manufactured in accordance with the PMA, CGMP, federal law and federal regulations.

165. Defendants expressly warranted to Plaintiff that the Cochlear Implant was of merchantable quality, reasonably fit for the purpose or purposes of for which it was supplied by Defendants, and that it would be free from defects in design, workmanship, and materials.

166. At the time of making the express warranties, Defendants had knowledge of the purpose for which the Cochlear Implant was to be used and warranted the same to be, in all respects, fit, safe, effective, and proper for such

purpose, and further that the Cochlear Implant had been manufactured in accordance with the PMA, CGMP, federal law and federal regulations.

167. Plaintiff reasonably relied upon the claimed skill and judgment of Defendants, the self-proclaimed "leading global expert in implantable hearing solutions" and upon said express warranty, in electing to have the Cochlear Implant surgically implanted.

168. The Cochlear Implant manufactured and sold by Defendants did not conform to these express warranties, and it caused injury and damage to Plaintiff when used as recommended and directed.

169. Defendants violated 21 U.S.C. § 331(a) by introducing and delivering Plaintiff's Cochlear Implant, an adulterated and misbranded medical device, into interstate commerce.

170. The Cochlear Implant was not of merchantable quality, reasonably fit for the purpose or purposes for which it was supplied by Defendants, because the hermetic seal failed, for the reasons set forth herein.

171. Defendants expressly warranted that they would replace the Cochlear Implant; or pay for the cost of repair of the Cochlear Implant; or pay for the replacement of the Cochlear Implant; or provide a refund or credit for the cost of the Cochlear Implant.

172. Defendants failed to perform their obligations under the express warranty.

173. According to Defendants' warranty to Plaintiff, the Cochlear Implant was supplied to Plaintiff/her clinic/her clinician subject to Defendants' standard conditions of sale.

174. Defendants' express warranty advised Plaintiff that if Plaintiff had an inquiry, to please contact the nearest Cochlear distributor, or Cochlear, at one of the customer service addresses nearest to Plaintiff, "listed below," Listed below is CUSTOMER SERVICE; COCHLEAR AMERICAS, 13059 East Peakview Avenue, Centennial, Colorado 80111. Alternatively, Plaintiff was directed in the express warranty to contact "Cochlear" at one of the addresses "nearest to you that are listed on the back cover." The supplier of the Cochlear Implant is referred to as "Cochlear" in the express warranty.

175. Within a reasonable time after discovering the breach of said express warranty, Plaintiff notified Defendants of the breach.

176. As a direct and proximate result of Defendants' breach of an express warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

EIGHTH CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

177. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

178. At the time Defendants designed and/or manufactured and/or marketed and/or sold and/or distributed the Cochlear Implant for use by Plaintiff, Defendants knew of the use for which the Cochlear Implant was intended and

impliedly warranted it to be of merchantable quality and safe for such use and that its manufacture complied with the PMA, CGMP, federal law and federal regulations

179. Plaintiff and/or Plaintiff's physicians reasonably relied upon the skill and judgment of Defendants as to whether the Cochlear Implant was of merchantable quality and safe for the intended use and upon Defendants' implied warranty as to such matters, specifically that Defendants had complied with the PMA, CGMP, federal law and federal regulations with respect to the Cochlear Implant's manufacture.

180. Plaintiff was prescribed, purchased, and received the Cochlear Implant for its intended use.

181. Contrary to such implied warranty, the Cochlear Implant was not of merchantable quality or safe for its intended use, because it was adulterated and defective as described above, in that Defendants failed to comply with the PMA, CGMP, federal law and federal regulations with respect to the Cochlear Implant's manufacture.

182. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

NINTH CAUSE OF ACTION:
NEGLIGENT MISREPRESENTATION

183. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

184. In the exercise of ordinary care, Defendants knew or reasonably should have known that the Cochlear Implant's manufacture failed to comply with the PMA, CGMP, federal law and federal regulations, yet Defendants negligently misrepresented to Plaintiff and/or Plaintiff's physicians that the Cochlear Implant's manufacture complied with the PMA, CGMP, federal law and federal regulations.

185. Plaintiff and/or Plaintiff's physicians reasonably relied to their detriment upon Defendants' misrepresentations and omissions that the Cochlear Implant's manufacture complied with the PMA, CGMP, federal law and federal regulations.

186. As a direct and proximate result of Defendants' negligent misrepresentations and omissions and/or their failure to disclose their violations of the PMA, CGMP, federal law and federal regulations applicable to the Cochlear Implant's manufacture, Plaintiff was implanted with the Cochlear Implant and suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future as a result thereof.

WHEREFORE, Plaintiff request judgment against Defendants, Cochlear Limited, an Australian public company, and Cochlear Americas Corporation, a Delaware corporation, jointly and severally as follows:

a. Awarding Plaintiff general and special compensatory damages in excess of this Court's minimum jurisdictional amount, as well as punitive damages as a result of the wrongs alleged herein;

b. Awarding reasonable attorney's fees and costs;

c. Awarding pre-judgment and post-judgment interest; and

d. Any and all further relief, both legal and equitable, that this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial pursuant to Federal Rule of Civil Procedure 38(b) on all issues so triable in this action.

February 25, 2014

Respectfully submitted,

PAMELA PAWLIK

s/ John Sawin

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CERTIFICATE OF SERVICE

I hereby certify that on February 25, 2014, I electronically filed the foregoing Plaintiff's First Amended Complaint with the Clerk of the Court for the United States District Court for the Northern District of Illinois by using the CM/ECF system, which will send notification of such filing to the following attorneys of record:

John Sawin (jsawin@sawinlawyers.com), Attorney for Plaintiff

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s/John Sawin
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