

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE**

LOGAN ESTEP, a minor b/n/f)	
CARL ESTEP and MELANIE ESTEP, parents,)	
and CARL ESTEP AND MELANIE ESTEP,)	
Individually,)	
)	
Plaintiff,)	Civil Action No. 2:09-cv-119
)	JUDGE HAYNES
v.)	
)	
ADVANCED BIONICS, LLC,)	
)	
Defendant.)	

AMENDED COMPLAINT

Plaintiffs, Carl Estep and Melanie Estep, Individually, and as parents of Logan Estep, a minor, bring this action pursuant to applicable statutory and common law against Defendant Advanced Bionics, LLC, and says for their Amended Complaint as follows:

SUMMARY OF THE ACTION

1. Logan Estep (“Logan” or the “Minor Plaintiff”) suffered from permanent hearing loss and was forced to undergo a lengthy and risky open-head surgery as a result of the failure of an Advanced Bionics HiRes 90k medical device (the “Device”) recalled by its manufacturer, Advanced Bionics, because it contained a manufacturing defect in a component supplied by AstroSeal, Inc., and was, therefore, not in compliance with applicable federal law, including federal device manufacturing requirements.

2. Advanced Bionics and AstroSeal violated the basic principal of biomedical engineering that moisture is to be avoided in electronic devices implanted in the human body. Advanced Bionics sold cochlear implants, medical devices used to provide a sense of sound to persons with profound hearing loss, that leaked. Advanced Bionics' specification for moisture content was 0.5%, yet Logan's failed device contained moisture far in excess of the limit. Water entered Logan's Advanced Bionics' implant through a leak in an AstroSeal manufactured component, causing device failure and requiring revision surgery. Advanced Bionics, at the time of Logan's revision surgery, had recalled all of its unimplanted devices containing the AstroSeal component.

3. The Advanced Bionics Device placed in Logan's head was designed, manufactured, and sold in violation of federal law and in violation of Advanced Bionics' federally-approved device specifications. It contained a latent defect not disclosed to the Food and Drug Administration ("FDA"), was adulterated, breached Advanced Bionics' express and implied warranties, and was defective and unreasonably dangerous for its intended use. Advanced Bionics was negligent in the design, manufacture and labeling of the Device and the AstroSeal component meant to provide a hermetic (waterproof) seal. Advanced Bionics knew that its devices were failing at an alarming and unacceptable rate as a result of moisture intrusion, had been cited by the FDA for violating federal manufacturing regulations, and yet Defendant continued to produce defective devices knowing full well that it had not solved the moisture problems with its product. Advanced Bionics was, at the least, "reckless" as that term is defined in Hodges v. S.C. Toof and Company, 833 S.W. 2d 896 (Tenn. 1992).

4. The FDA filed an administrative enforcement action against Advanced Bionics and key employees for selling devices of the exact same type given to Logan because those

devices were not FDA approved for sale in the United States and manufactured in violation of federal law. Advanced Bionics settled this FDA action, paying \$1.1 million on behalf of the company and \$75,000 on behalf of then-CEO Jeffrey Greiner, individually.

5. Defendant is liable to Plaintiff for all consequential damages Plaintiffs have incurred as a result of injuries to Logan. Defendant is liable for Logan's pain, suffering, temporary and permanent hearing loss, revision surgery, loss and/or delay in Logan's ability to articulate, and punitive damages. Defendant is liable for any and all other damages sustained by Plaintiffs. Plaintiff demands trial by jury.

PARTIES

6. Plaintiffs are adult resident citizens of Cookeville, Putnam County, Tennessee.

7. The Minor Plaintiff is a resident of Cookeville, Putnam County, Tennessee.

8. Defendant Advanced Bionics, LLC is a Delaware limited liability company with a principal place of business in Valencia, California. Advanced Bionics, LLC has done and continues to do business as Advanced Bionics Corporation and is a corporate successor to prior entities using the name "Advanced Bionics" for all purposes relevant to this Complaint subject to all liabilities relative to the Complaint attributable to a prior entity known as Advanced Bionics Corporation, a Delaware corporation that was at one time a wholly-owned subsidiary of Boston Scientific Scimed, Inc.

GENERAL ALLEGATIONS

I. Cochlear implants are prosthetic hearing devices.

9. A cochlear implant is a Class III medical prosthesis designed to enable profoundly deaf persons to “hear” by directly stimulating auditory nerves leading to the brain by means of an electrode array strategically positioned in the cochlea of the inner ear.

10. Unlike hearing aids, cochlear implants do not amplify sound; instead, a miniature computer/sound processor, worn outside the body, selectively processes sound into coded signals. Such signals are transmitted by wireless electromagnetic conduction to an implantable cochlear stimulator (ICS) that is surgically implanted in the patient’s body.

11. The ICS receives these coded signals and interprets them using its sophisticated microelectronic architecture to send specialized patterns of electrical current to the electrodes inserted inside of the cochlea. Multiple electrodes along the length of the electrode array emit electrical currents in the form of electrical stimulation pulses to the surrounding hearing nerve receptors based on scientific knowledge that different parts of the cochlear are sensitive to different sound frequencies. Nerve fibers then send this information to the brain for central processing, interpretation, and perception as sound.

12. Cochlear implant surgery requires general anesthesia and often involves a procedure called a mastoidectomy, in which an incision is cut and an indent is drilled into the skull to allow the attachment of the implant. Once the implant is attached, the electrode array is inserted in the delicate coiled cochlea of the inner ear by making a hole called a cochleostomy and inserting the electrode array and pushing it through as gently as possible to avoid trauma to the inner surfaces. Post-surgery vertigo and nausea are common. Paralysis of the facial nerves is a rare but possible risk of surgery, as is tinnitus and damage to the vestibular system.

13. After surgery, initial programming of the external processor is not done until the incision has healed, which typically takes two to five weeks. At such initial stimulation and programming, the individual electrodes are programmed at appropriate threshold and amplitude levels based on the patient's response to stimulation which is then used to create an electrode "map." Once all of the electrodes are mapped, the processor is turned on and the cochlear implant patient can "hear." This programming process continues to be fine-tuned at later appointments throughout the first year with the external processor eventually being programmed with multiple maps for different auditory environments.

14. In normal hearing, the cochlea is stimulated by hundreds of thousands of hair cells. The stimulation of the cochlea through implanted electrodes is very different. Thus a cochlear implant demands a long rehabilitation period in which the cochlear implant recipient's brain must learn how to decode and recognize sound.

15. The perception of sound by cochlear implant users is very different from normal hearing. Cochlear implant patients who have lost their hearing often describe the initial stimulation as hearing tinny "buzzes" and "whistles" that had no relation to what they remembered as sound and felt that they would never be able to comprehend.

16. Gradually through aural rehabilitation and listening experience, the brain may learn to decode sound. Over time, some cochlear implant recipients learn to distinguish sounds well enough so that they can talk on the telephone through the cochlear implant or listen to TV without closed-captioning.

17. When a defective cochlear implant is replaced, the electrode array may not be re-implanted in the same position in the cochlea, leading to different threshold and amplitude settings. As a result, rather than starting off by "hearing" at the comprehension level where the defective implant failed, a cochlear implant patient may have to go through a second aural rehabilitation before the replacement implant functions at the same level as the first implant did.

18. There is no guarantee that a replacement cochlear implant will ever function at the same level as the first. In some cases, due to cochlea scarring or nerve damage from explant

surgery, different electrode positioning, or other causes, a cochlear implant patient may not function as well with the replacement implant.

19. Different cochlear implant manufacturers use different sound strategies. Thus when a defective implant is replaced with a new device by a different cochlear implant manufacturer, an entire new sound system needs to be learned.

20. Bilateral implantation, in which cochlear implants are surgically implanted in both ears, is increasingly becoming a desirable option for young children based on recent clinical research findings. The reasoning is that bilateral sound assures that sound is processed through both sides of the brain, which enables the brain to mature and to learn to process bilateral information during a period where maximum brain plasticity and linguistic development occurs.

II. Moisture causes failure to cochlear implants.

21. Moisture is a well-known cause of failure of electronic circuits.

22. Moisture causes corrosion, dendrite growth, and other processes that damage electronic circuits and cause them to fail.

23. Implantable medical devices, such as cochlear implants, are exposed to more moisture than most electronic devices because the human body is a very wet and salty (saline) environment.

24. The human body is more than fifty percent (50%) water.

25. To function reliably electronic circuits inside cochlear implants should be clean, dry, and free of moisture.

26. It is critical that a cochlear implant not allow moisture in, or any toxic compound out.

27. The failure of a cochlear implant requires surgery to remove and replace the failed implant.

28. Revision surgery risks damage to the cochlea, permanent loss of hearing, infection and other complications.

29. Moisture inside a cochlear implant may have been sealed in during the manufacturing process, leaked in at some point afterwards (including after the device was implanted in a patient), or both.

30. There is no other way moisture can enter a device.

31. A variety of techniques exist to determine the effectiveness of the seal (whether the seal is water proof or hermetic) of microelectronic devices with designed internal cavities. A designed internal cavity is the void space inside the device.

32. A variety of techniques exist to determine the moisture content (for example, the percentage of water vapor) within sealed microelectronic devices with designed internal cavities.

33. Residual gas analysis (“RGA”) is an analytical technique used primarily for hermeticity quality assurance and failure analysis purposes. In RGA, the test device is placed in a sealed chamber and punctured. The interior gases are sucked out and analyzed. The RGA can reveal, for example, the percentage of water vapor within a sealed medical device.

34. The RGA and other techniques to evaluate the hermeticity of a device may provide data to determine if, and why, a device leaked. Such techniques can also be used to determine if a device was properly assembled in the first place.

35. To adequately validate a device for moisture content and hermeticity requires testing of production lots under actual or simulated use conditions.

36. At all relevant times Advanced Bionics knew that federal law required its medical devices to be water proof, hermetically sealed, and without excessive moisture content.

37. Device failure can occur in a cochlear implant when the percentage of moisture vapor in a device is greater than five percent (5%).

III. Advanced Bionics' HiResolution Cochlear Implant.

38. Advanced Bionics manufactured and sold a cochlear implant system referred to as the "HiResolution Bionic Ear System." The HiResolution system was marketed as an improved version of Advanced Bionics' former "CLARION Multi-Strategy Cochlear Implant."

39. The implant component of the system was the implantable cochlear stimulator (the "ICS").

40. The ICS consisted of a "can," a sealed titanium metal housing containing an electronic circuit, an electrode (an insulated wire) that goes into and stimulates the cochlea, and an antenna to receive signals from the external processor.

41. The ICS included a feed-thru (also a feed-thru or feed-thru) assembly. The feed-thru kept moisture from entering the implant and connected the electronic circuit inside the implant to the electrode through a water proof fitting.

42. Advanced Bionics has used two different feed-thru suppliers on its cochlear implant device, Pacific Aerospace & Electronics, Inc. ("PA&E") and AstroSeal.

43. Both suppliers were supposed to provide interchangeable feed-thru assemblies meeting the same high standard of functionality and Advanced Bionics' specifications, including that the feed-thru provide a water proof and hermetic seal during the implant's anticipated 10-year life span.

44. Advanced Bionics added AstroSeal as a feed-thru supplier without receiving approval from FDA.

IV. Federal Regulations

45. The removal of devices from the market and other corrective actions taken by Advanced Bionics are product recalls under federal regulations.

46. Under federal regulations, a “[r]ecall means a firm’s removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure.” 21 C.F.R. Part 7.3(g).

47. A 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 regulations pursuant to 21 U.S.C. § 351 and 21 C.F.R. Part 820.1(c).

48. A device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular way, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

49. Advanced Bionics is required to comply with applicable FDA regulations, including FDA regulations relating to records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of its medical devices.

50. Adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to

death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. *See* 21 C.F.R. Part 803.50.

51. Manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to the FDA as a removal or correction of the device. *See* 21 C.F.R. Part 803.52.

52. Manufacturers must report to the FDA in five business days after becoming aware that a medical device reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. Medical device reportable events require the manufacturer to conduct a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. *See* 21 C.F.R. Part 803.53

53. Device manufacturers must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of federal law caused by the device that may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that

have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 C.F.R. Part 806.10.

54. Pursuant to federal regulations, the CGMPs require compliance with the following quality system regulations:

- a. Manufacturers must meet design-control requirements, including without limitation, conducting design verification and validation to ensure that devices conform to defined use needs and intended uses;
- b. Manufacturers must establish purchasing controls to ensure that all purchased products, parts and components conform to specified requirements;
- c. Manufacturers must meet quality standards in manufacturing and production;
- d. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions;
- e. Manufacturers must investigate the cause of nonconforming product and take corrective action to prevent recurrence;
- f. Manufacturers are required to review and evaluate all complaints and determine whether an investigation is necessary;
- g. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance.

See generally 21 C.F.R. Part 820.

55. The CGMPs required that Advanced Bionics sufficiently evaluate and select AstroSeal as a supplier of feed-thru assemblies on the basis of its ability to meet specified device

requirements, including quality requirements, related to its intended long-term use in the human body. 21 C.F.R. Part 820.50(a).

56. The CGMPs required that Advanced Bionics adequately validate all HiRes 90k devices by testing production lots under actual or simulated use conditions. 21 C.F.R. Part 820.30(g).

57. The CGMPs required Advanced Bionics to investigate the cause of moisture in its HiRes 90k implants and to take corrective action to prevent reoccurrences and to investigate clinical complaints from patients reporting erratic or non-functioning implants.

58. As stated above, a manufacturer's failure to comply with CGMPs applicable to a device renders the device adulterated under the FDCA., 21 U.S.C. § 351(h); 21 C.F.R. Part 820.1(c). Each introduction of an adulterated device into interstate commerce is a violation of the FDCA. 21 U.S.C. § 331(a).

59. A device is deemed adulterated if the methods used in, and the facilities and controls used for, its manufacture, packing, storage, and installation are not in conformity with CGMP requirements. Each introduction of an adulterated Device into interstate commerce is a violation of federal law. 21 U.S.C. § 331(a).

V. Pre-Market Approval (PMA) Process.

60. FDA regulations require manufacturers to submit Pre-Market Approval Application ("PMA") supplements for changes that may affect the safety or effectiveness of a device, including "[t]he use of a different facility or establishment to manufacture" the device, and "[c]hanges in the performance or design specifications, circuits, components, ingredients,

principle of operation, or physical layout of the device.” 21 C.F.R. Part 814.39(a)(3) and (6). Such supplements are referred to as “180-day PMA supplements.”

61. Any change in specifications of the materials used in manufacture requires a 180-day PMA supplement.

62. A manufacturer may make a change to a device without filing a PMA supplement *only* if the change does not affect the device’s safety or effectiveness and the change is reported to FDA in post-approval periodic reports. 21 C.F.R. Part 814.39(b).

63. A feed-thru can affect the safety and/or effectiveness of a cochlear implant.

64. A device lacking necessary PMA approval (including approval of supplements) is deemed adulterated. 21 U.S.C. § 351(f)(1)(B).

65. Federal regulations require that a PMA supplement be submitted when unanticipated adverse effects increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification. *See* 21 C.F.R. Part 814.39.

66. Advanced Bionics first received PMA approval to manufacture cochlear implants for adults in 1996. The HiRes 90k was not approved as a separate Class III device, but was approved in the Thirtieth PMA supplement submitted by Advanced Bionics on July 7, 2003.

67. The July 2003 PMA listed as a “Conditions of Approval” that before Advanced Bionics made any changes affecting the safety or effectiveness of a device, it would submit a PMA supplement for review and approval by the FDA. This requirement in the July 2003 PMA was in accordance with FDA rules and regulations stating the same. *See* 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. Part 814.39(a).

68. Advanced Bionics was well aware of the PMA Supplement requirement. Not only was this requirement listed in all of Advanced Bionics' previously approved PMAs, but in 2001, the FDA had issued a List of Inspectional Observations ("Form FDA-483") related to an on-site inspection of Advanced Bionics' Sylmar, California facility related to hermeticity failure in an earlier model. In this Form FDA-483, the FDA listed Advanced Bionics' failure to file PMA supplements for four separate testing, manufacturing process, and design changes as violations of FDA regulations.

69. As part of the July 2003 HiRes 90k PMA, the FDA approved of the design of the internal ICS of the HiRes 90k implant which was housed in a hermetically sealed (i.e. moisture-proof and airtight) titanium case attached to crucial component called the feed-thru assembly. As already alleged above, the feed-thru is the component that conducts electrical signals from the hermetically (waterproof) sealed part of the ICS to the electrode array.

70. The feed-thru, as a critical component to Advanced Bionics' cochlear implant HiRes 90k, performs the critical task of connecting the internal electronic circuit board to the implanted electrodes through a series of pins which form the electrical path to the electrode array.

71. Equally important, the feed-thru assembly is supposed to prevent internal body moisture from entering the implant by creating a hermetically (i.e.) water-proof and moisture proof barrier between the ICS internal circuitry and the electrodes. As such, the FDA approved specifications for the HiRes 90k required that Advanced Bionics ensure that conditions similar to its expected long term use in the human body:

- a. that the HiRes 90k device would be "hermetically sealed" to prevent water intrusion;

- b. that the HiRes 90k device would have a leak rate of less than 1×10^{-9} cc-atm/s of helium;
- c. that the HiRes 90k device be 100% tested at the time of manufacture for hermeticity;
- d. that the HiRes 90k device would contain no more than 0.500% (5,000 ppm) moisture; and
- e. that the HiRes 90k and Clarion 1.2 devices be sealed with an inert gas mixture, 25% helium and 75% argon.

72. Upon information and belief, during the PMA approval process, Advanced Bionics submitted design data and documents relating to the use of PA&E a/k/a Supplier A as the supplier of the critical feed-thru component.

73. After receiving the July 2003 PMA approval for the HiRes 90k based on only PA&E data, Advanced Bionic began using AstroSeal a/k/a Vendor B as a supplier of the HiRes 90k feed-thru.

74. The specifications of the AstroSeal feed-thru differed from the PA&E in at least four ways:

- a. the composition of AstroSeal's glass seal was different, resulting in a different rate of thermal expansion in the glass;
- b. there was a different mechanical configuration to support the ceramic bead of the AstroSeal feed-thru;
- c. AstroSeal's feed-thru had a shorter glass seal;

- d. the glass for the AstroSeal feed-thru was fired through a vacuum bake for a different length of time and at a different temperature than was approved in the July 2003 PMA.

75. The changes in the AstroSeal design affected the safety and effectiveness of the HiRes 90k, yet Advanced Bionics neither filed a 180-Day PMA Supplement nor a 30-Day Notice under 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. Part 814.39. AstroSeal was not mentioned in any post approval periodic report under 21 C.F.R. Part 814.39(b).

76. Within six months from the time that Advanced Bionics started using AstroSeal as a feed-thru supplier, Advanced Bionics became aware of excess moisture in HiRes 90k implants implanted in the human body after such implants were returned to Advanced Bionics after being removed from patients' bodies either for medical reasons (such as implant rejection, infection, or other medical complications) or because of device failure.

77. This awareness occurred, in part, because the FDA required that Advanced Bionics perform specific testing, including hermeticity tests, on returned devices to understand the reason for device failure and to improve device reliability.

VI. Device Reporting.

78. Pursuant to federal regulations, manufacturers must report adverse events associated with a medical device to the FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to serious injury, or that a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the

device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. 21 C.F.R. Part 803.50.

79. Pursuant to federal regulations, Advanced Bionics must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to the FDA as a removal or correction of the device. 21 C.F.R. Part 803.52.

80. Pursuant to federal regulations, manufacturers must report to the FDA within five (5) business days after becoming aware that an MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. 21 C.F.R. Part 803.53. An MDR reportable event is, among other things, an event that makes a manufacturer aware that a device marketed by the manufacturer has malfunctioned or may have caused or contributed to a death or serious injury. 21 C.F.R. Part 803.3.

81. Similarly, device manufacturers must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of federal law caused by the device that may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or

distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. 21 C.F.R. Part 806.10.

82. Upon information and belief, pursuant to its approved PMA, Advanced Bionics must submit an “Adverse Reaction Report ” or “Device Defect Report ” within 10 days after Advanced Bionic receives or has knowledge of information concerning any “adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device ” and (a) has not been addressed by the device’s labeling or (b) has been addressed by the device’s labeling, but is occurring with unexpected severity or frequency.

83. Advanced Bionics must submit an “Adverse Reaction Report” or “Device Defect Report” pursuant to 21 C.F.R. Part 814.82(a)(9) within 10 days after Advanced Bionic receives or has knowledge of information concerning any “adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device” and (a) has not been addressed by the device’s labeling or (b) has been addressed by the device’s labeling, but is occurring with unexpected severity or frequency.

84. Advanced Bionics’ failure to meet the above-referenced federal requirements applicable to medical devices and Advanced Bionics’ other acts and omissions as described herein directly and proximately caused the subject device to be in violation of federal law, adulterated, unfit for sale, defective and unreasonably dangerous and the proximate and legal cause of harm to Plaintiff and her minor son.

85. Plaintiffs’ state law claims against Advanced Bionics are premised, *inter alia*, on Advanced Bionics’ violation of federal regulations, and are parallel state law requirements that do not conflict with and are not in addition to or different from federal requirements.

86. AstroSeal, as a manufacturer of components or parts of finished devices, was not subject to federal CGMP requirements set forth in the quality system regulation, 21 C.F.R. Part 820, although they were “encouraged to use appropriate provisions of the CGMP requirements as guidance,” pursuant to 21 C.F.R. Part 820.1(a).

87. The FDA required that the Device be hermetically sealed and free of moisture.

VII. The FDA required that the ICS be hermetically sealed and free of moisture.

88. Advanced Bionics’ federally approved manufacturing specification required that the Device be “hermetically sealed” to prevent water intrusion.

89. Advanced Bionics’ federally approved manufacturing specification required that the Device have a leak rate of less than 1×10^{-9} cc-atm/s of helium.

90. Advanced Bionics’ federally approved manufacturing specification required that the Device be 100% tested at the time of manufacture for hermeticity.

91. Advanced Bionics’ federally approved manufacturing specification required that the Device contain no more than 0.500% (5,000 ppm) moisture.

92. Advanced Bionics’ federally approved manufacturing specification required that the Device be sealed with an inert gas mixture, 25% helium and 75% argon.

93. The expected functional life span of the Device was at least 10 years.

94. Advanced Bionics expressly warranted the Device for 10 years.

95. To have any reasonable chance of operating over the anticipated 10-year life span, the Device must remain hermetically sealed and free of excessive moisture.

96. Advanced Bionics was required to comply with the CGMP, 21 C.F.R. Part 820, and other applicable FDA regulations.

97. The CGMP required that Advanced Bionics sufficiently evaluate and select AstroSeal as a supplier of feed-thru assemblies on the basis of its ability to meet specified Device requirements, as required by 21 C.F.R. Part 820.50(a).

98. The CGMP required that Advanced Bionics adequately validate Devices containing the AstroSeal feed-thru assemblies by testing production lots under actual or simulated use conditions, as required by 21 C.F.R. Part 820.30(g).

99. Advanced Bionics is and was required to qualify all critical components at the component level of a cochlear implant prior to implantation in the human body.

100. Advanced Bionics is and was required to qualify the HiRes 90k device using all critical components prior to implantation in the human body.

101. Advanced Bionics is and was required to test the HiRes 90k device in an environment that mimics the environment in which the device is to be implanted, i.e. the human body.

102. Advanced Bionics is and was required to conduct simulated life testing of the HiRes 90k prior to the device being implanted in the human body.

103. The helium leak test does not mimic the human body.

104. Advanced Bionics is and was required to validate the HiRes 90k using all critical components prior to the device being implanted in the human body.

105. Advanced Bionics is responsible for qualification of a medical device and its critical components, not the FDA.

106. Advanced Bionics is responsible for validation of a medical device, not the FDA.

107. Advanced Bionics is responsible for supplier quality and audits, not the FDA.

108. Advanced Bionics is responsible for performing failure analysis testing on returned (explanted) devices, not the FDA.

109. Advanced Bionics is responsible for tracking and trending reasons for device failure, not the FDA.

110. Advanced Bionics is responsible for determining the root cause of device failure, not the FDA.

111. Patient safety is paramount to profit at a medical device company.

112. It is reckless to place profits over people at a medical device company.

VIII. Advanced Bionics has known that the Device leaks since 2004.

113. In approximately July of 2003, Advanced Bionics commercially released the HiResolution cochlear implant in the United States.

114. Advanced Bionics received returned HiRes 90k implants including through September 2004.

115. Implants were removed and returned for medical reasons (for example, infection or other medical complications) or because of device failure.

116. Advanced Bionics performed hermeticity and moisture content testing on returned implants.

117. Advanced Bionics' reasons for testing returned implants included to understand the reason for device failure, to improve device reliability, and to comply with the CGMP and other applicable federal regulations applicable to medical Devices.

118. On February 12, 2004, Advanced Bionics performed an RGA on an explanted device. The RGA showed that the device had moisture in excess of 0.500%.

119. On April 14, 2004, Advanced Bionics performed an RGA on an explanted device. The RGA showed that the Device had moisture in excess of 0.500%.

120. Advanced Bionics opened an investigation to understand the reason(s) for excessive moisture inside the device.

121. In June 2004, Advanced Bionics employee Josh Polack visited Pernicka Corporation.

122. During the June 2004 Pernicka visit, or shortly thereafter, Advanced Bionics learned of at least two explants with RGA moisture/vapor percentage greater than five percent (5%).

123. By June 25, 2004, a total of fourteen (14) devices were tested, eight (8) of which (57%) contained moisture in excess of 0.500%. In one instance the moisture/vapor content in the device was 30%.

124. Advanced Bionics knew that its devices contained water above specifications at an alarming and unacceptable rate and that patients were, as a result, experiencing device failure at an excessive rate and suffering hearing loss and surgery to remove the failed devices.

125. As of the summer of 2004, Advanced Bionics attributed the root cause of moisture in most explanted devices to leaks after manufacture – the failure of the implant to maintain an effective hermetic seal.

IX. Advanced Bionics flunks 2004 FDA inspection.

126. From August 25 to September 15, 2004, the FDA inspected Advanced Bionics' manufacturing facility in Sylmar, California.

127. On September 15, 2004, the FDA issued FDA-483 observations identifying non-conformities and weaknesses in Advanced Bionics' quality system that required improvement.

128. The FDA identified twenty-three (23) objectionable practices by Advanced Bionics in connection with the company's cochlear implants.

X. Advanced Bionics issued its first Device recall in September of 2004.

129. On September 27, 2004, as a result of the FDA inspection, Advanced Bionics initiated a Class II Recall of all of its un-implanted CLARION and HiResolution Devices, Recall Number Z-0046-05, due to the "potential presence of moisture in the internal circuitry, which can cause the device to stop functioning."

130. Advanced Bionics suspended shipment of new devices until November 8, 2004.

131. All improvements to the vacuum bake-out process were inactivated by November 1, 2004.

XI. The FDA found that Advanced Bionics' Devices were adulterated.

132. On February 1, 2005, the FDA took further action against Advanced Bionics' cochlear implant business, issuing it a "Warning Letter" identifying eighteen (18) "significant deviations" from federal regulations in the "manufacturing, packaging, storage or installation" of medical Devices. A copy of the Warning Letter is attached as Ex. A.

133. The FDA reported to Advanced Bionics that its inspection "disclosed that your devices are adulterated" within the meaning of Section 501(h) of the Federal Food, Drug and Cosmetic Act.

134. The FDA reported that Advanced Bionics was in violation of the CGMP regulations for medical devices set forth in the quality system regulation, specified in 21 C.F.R. Part 820.

135. The FDA findings in the February 1, 2005 Warning Letter included:

- a. that Advanced Bionics' quality system failed "to control moisture limits within the hermetically sealed cochlear implants;"
- b. that "[t]here is inadequate knowledge regarding how [RGA] results can be used to determine if the device was hermetically sealed with water within the device at the time of manufacture or if the water entered the Device as a result of a loss of hermeticity;"
- c. that Advanced Bionics failed to document the 0.500% (5,000 ppm) "water content limit for the [device]" in a design document;
- d. that Advanced Bionics failed to implement a verification and validated process for the device to ensure it met the water content limit of 0.500% (5,000 ppm);
- e. that Advanced Bionics failed to perform a complete risk analysis in connection with device failures that may result from a loss of hermeticity (i.e., a leak) or moisture trapped in the device during manufacturing;
- f. that Advanced Bionics failed to validate manufacture processes to ensure that devices identified with moisture were hermetically sealed and that non-hermetically sealed Devices were identified as unacceptable for distribution and implantation;
- g. that Advanced Bionics failed to sample and test products to ensure that they were hermetically sealed in compliance with the moisture specification; and
- h. that Advanced Bionics failed to identify appropriate corrective action to prevent recurrence of non-conforming product.

136. The FDA reported to Advanced Bionics that “[u]ntil you have adequately demonstrated that you have corrected the violations . . . we continue to believe that the violations still pose a significant risk to public health.”

137. The FDA directed that Advanced Bionics take “prompt action to correct these deviations” and that failure to do so may result in “seizure, injunction, and/or civil penalties.”

138. The Warning Letter remained in place until early 2006.

XII. Internal audits found serious ongoing quality problems at Advanced Bionics.

139. Shortly after the FDA Warning Letter, Boston Scientific, the corporate parent of Advanced Bionics at the time with a principal place of business in Natick, Massachusetts, performed an internal investigation and audit of quality control at Advanced Bionics.

140. The audit discovered seven (7) major non-conformities and many uncorrected issues remaining from the 2004 Form 483 observations issued by the FDA.

141. On January 25, 2006, the FDA issued Boston Scientific a corporate-wide Warning Letter.

142. This letter, only the third ever issued in the history of the FDA, placed a heavy burden on Boston Scientific. All subsidiaries and divisions of the company were subject to the Warning Letter, including Advanced Bionics at that time.

143. In February of 2006, Boston Scientific contracted with an independent quality auditor, Quality Hub, to do an onsite audit of Advanced Bionics to verify the adequacy and completeness of Advanced Bionics corrective actions related to the 2004 Form 483 and the 2005 Warning Letter observations.

144. The Quality Hub audit uncovered numerous deficiencies at Advanced Bionics. Advanced Bionics has admitted this fact.

145. On May 5, 2006, Advanced Bionics issued a formal response to the audit report, noting that “[Bionics’ management] agrees that its organizational structure does not sufficiently demonstrate that quality is the company’s first priority.”

146. As a result of the audit, Advanced Bionics undertook a corporate reorganization meant to improve quality control.

147. Advanced Bionics failed to timely correct deviations noted by the FDA and by its internal auditors.

148. At all relevant times, Advanced Bionics remained out of compliance with federal requirements.

149. Advanced Bionics knew that device failures continued to occur in 2005 and 2006 at an alarming rate as a result of moisture inside the devices.

150. Advanced Bionics knew that the manufacturing process and quality changes it had implemented in 2004 and 2005 had not solved its moisture problem.

151. Advanced Bionics recklessly, maliciously, and outrageously continued to market and sell cochlear implants in 2003, 2004, 2005 and early 2006 despite knowing that the devices had a moisture problem, having repeatedly been cited by the FDA for violations of federal regulations, including the CGMP, and yet Advanced Bionics failed (1) to properly test, qualify and validate the HiRes 90k device using an AstroSeal feed-thru, (2) to disclose the use of AstroSeal to the FDA and (3) to identify the root cause of the moisture problem and solve it in time to prevent Logan from receiving a leaky Device that failed because of water intrusion.

XI. Advanced Bionics issued its second and third Device recalls in March 2006.

152. On March 8, 2006, Advanced Bionics initiated two Class II recalls of all unimplanted HiResolution cochlear implants containing feed-thru assemblies manufactured by

AstroSeal, Recall Number Z-0759-06 for Model number CI-1400-2H and Recall Number Z-0758-06 for Model Number CI-1400-01.

153. Advanced Bionics initiated the recall because it belatedly acknowledged that devices containing the AstroSeal feed-thru were causing premature device failure and temporary and permanent hearing loss, pain, and suffering to patients and requiring surgery to remove and replace defective implants.

154. Advanced Bionics also initiated the recall because the devices containing the AstroSeal feed-thru were out of compliance with federal requirements and the CGMP.

155. Devices containing the AstroSeal feed-thru were adulterated, misbranded, and non-compliant with the company's own standards and FDA-approved specifications.

156. Advanced Bionics determined that moisture was not entering its implants during its manufacturing process, but instead, that moisture was leaking into the device through a defective feed-thru assembly manufactured by AstroSeal after the devices had been shipped and implanted in patients.

157. Advanced Bionics determined that the feed-thru manufactured by AstroSeal failed to reliably maintain a hermetic seal resulting in moisture content inside the devices above the company's 0.500% specification.

158. The defective AstroSeal feed-thru, according to Advanced Bionics, came to light after the product reached market and was not included or referenced in any manner in connection with the company's filings with the FDA.

159. Advanced Bionics failed to include any warning or labeling to the effect that its devices were not hermetically sealed and contained excessive moisture.

160. Instead of the inert argon and helium gas that was supposed to be present inside the devices, they contained water.

161. The AstroSeal feed-through, according to Advanced Bionics, “was not designed and built to effectively keep moisture out.”

162. The AstroSeal feed-thru, according to Advanced Bionics, “did not meet our standards.”

163. According to Advanced Bionics’ Summer 2007 Auditory Reliability Report, 79.8% of Devices containing the Astro-Seal feed-thru were functional after 3 years.

164. For a Device warranted to last 10 years, failure of 20% of the Devices containing the AstroSeal feed-thru after 3 years as a result of moisture intrusion is an outrageous and catastrophic failure rate not approved by FDA and unacceptable by any standard of reliability, including Advanced Bionics’ own standard.

165. By contrast, according to Advanced Bionics, its devices manufactured with a PA&E feed-thru have a failure rate of 1.5% after 3 years.

166. Advanced Bionics had information on the problem with the AstroSeal feed-thru assembly prior to March of 2006, but failed to timely notify the FDA and the medical community and patients and failed to take appropriate action to prevent harm to patients receiving the device.

167. Some Advanced Bionics employees received “earn out” payments based on the sale of defective HiRes 90k cochlear implants with an AstroSeal feed-thru.

168. These “earn out” payments totaled millions of dollars.

169. The Devices containing AstroSeal feed-thru assemblies were defective, negligent, unreasonably dangerous, and not in compliance with any applicable standard or regulation,

including FDA-approved device manufacturing specifications and CGMP regulations promulgated by the FDA.

XII. FDA files an enforcement action against Advanced Bionics for violating federal law.

170. The FDA filed a complaint against Advanced Bionics in November 2006 seeking penalties against Advanced Bionics and its President and then Co-CEO Jeffrey H. Greiner.

171. The FDA amended its complaint on March 17, 2007.

172. The amended complaint sought a \$2.2 million penalty against Advanced Bionics for violating federal law, including the CGMP standards and failure to notify the FDA of a change in an outside supplier of the feed-thru component to Astro-Seal, thereby exposing recipients of the device to unnecessary health risks.

173. The FDA announced that the device poses a “public health risk due to excessive moisture, exposing patients to the risk of device failure, possible surgery, and the potential for additional hearing loss.” A copy of the Amended Complaint is attached as Ex. B.

174. According to the FDA, Advanced Bionics CGMP violations include “the failure to sufficiently evaluate and select a new vendor as the supplier of a critical Device component and the failure to adequately validate the continued safety and effectiveness of the hearing aid by testing lots under actual or simulated use when the unapproved vendor’s component was used.”

175. According to the FDA, “Advanced Bionics shipped hearing aids in violation of the law between January 2005 and July 2006.”

XIII. Logan received a defective Device containing an AstroSeal component.

176. Logan had sustained profound hearing loss by the age of 2 years.

177. The Estep family tried hearing aids for Logan, but the hearing aids did not help.

178. Logan was implanted with an Advanced Bionics HiRes 90k cochlear device on December 2, 2003 with initial stimulation approximately one month later. Surgery was performed in Knoxville, Tennessee.

179. Advanced Bionics failed to warn Plaintiffs, Logan's surgeon, or the medical facility at which Logan's operation was performed that this Device was manufactured and marketed after Advanced Bionics knew that it had added AstroSeal as a feed-thru supplier without FDA approval, that Logan was receiving an untested, invalidated and unqualified Device with an AstroSeal feed-thru, or that Logan was receiving an "adulterated" and experimental Device as that term is defined by FDA regulations.

180. Plaintiffs never received a letter from Advanced Bionics advising them that Logan's HiRes 90k Device was being recalled in September 2004. Advanced Bionics concealed the information it had in-hand about the startling failure rate in the HiRes 90k due to moisture infiltration. Plaintiffs were also not advised that the AstroSeal feed-thru was unqualified, invalidated and not tested under life or simulated use conditions.

181. Logan never received an optimal result with the Device.

182. In approximately June 2006, Plaintiffs received a second letter from Advanced Bionics advising of a second recall. Plaintiffs were still told nothing related to the use of an unapproved critical component or the number of moisture-related failures.

183. Logan's device failed as a result of water intrusion into the device through nuero cracks in the oxide layer of an AstroSeal feed-thru. The RFA testing on Logan's failed device revealed the device had a staggering 41.0199% water/vapor at the time of testing. Advanced Bionics confirmed in a Failure Analysis Report that Logan's device was a "confirmed

Device Failure” and that “The source of the problem [in the device] was a feed-thru hermeticity issue from one feed-thru under [AstroSeal].”

XIV. Logan underwent replacement surgery in 2009.

184. On September 16, 2008, John Little, M.D., performed explant surgery to remove the defective Device. Dr. Little replaced the defective Device with another Advanced Bionics product.

185. The explant and reimplantation surgery which Logan was forced to undergo is a surgery performed under a general anesthetic involving opening of the skull, a procedure necessarily involving serious health risks and requiring a number of hours to perform.

XV. Advanced Bionics Failure Analysis Report established Device defectiveness

186. After the Device was explanted by Dr. Little, it was returned to Advanced Bionics for testing. Those tests, upon information and belief, were conducted at the laboratories of Advanced Bionics as well as an independent laboratory in Colorado.

187. Advanced Bionics issued its Failure Analysis Report of Logan’s explanted Device concluding that an excessive amount of water/vapor, well above the .5% limit, had infiltrated the Device causing the failure.

188. The Failure Analysis Report reached the determination of “root cause” of Logan’s Device failure as being excessive moisture causing shorting of the electrical circuits in the Device, the source of the problem being a feed-thru hermeticity issue from vendor AstroSeal.

COUNT I
NEGLIGENCE

189. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiffs’ Complaint as if fully set forth herein.

190. At all relevant times, Defendant had a duty and continue to owe a duty to Plaintiffs and their son: (a) to provide a safe Device, both initially and upon reimplantation, in design and manufacture, (b) to notify the FDA of design flaws, (c) to manufacture the Device properly in compliance with applicable regulations and FDA-approved specifications, and (d) to warn the FDA and Plaintiff of the defective nature of the Device and that the Device is not hermetically sealed and/or is not free of excessive moisture.

191. Defendant breached its duty of reasonable care to Plaintiffs by incorporating a defect into the design of the Device, by failing to manufacture the Device within the standard of care, by failing to properly test, validate and qualify the feed-thru and device and by failing to warn Plaintiffs of the risk that the Device would not be hermetically sealed and free of excessive moisture, thereby causing Plaintiffs' injuries.

192. Defendant breached its duty of reasonable care to Plaintiffs by manufacturing and assembling the Device in such a manner that they were not hermetically sealed, contained moisture, allowed moisture to leak in after the Device has been implanted, and would, therefore, short circuit, corrode, or otherwise malfunction and expose patients, including Logan, to loss of hearing, unnecessary surgery, to life-threatening physical trauma, pain and suffering and developmental loss or delay.

193. Defendant breached its duty of reasonable care to Plaintiffs by failing to notify and warn the FDA, Logan's treating physicians, Plaintiffs and the public at the earliest possible date of known design or manufacturing defects in the Device.

194. Defendant breached its duty of reasonable care to Plaintiffs by failing to exercise due care under the circumstances.

195. Defendant breached its duty by failing to qualify and validate the HiRes 90k with an AstroSeal feed-thru.

196. Defendant breached its duty by failing to test the HiRes 90k with an AstroSeal feed-thru under actual or simulated use conditions before implantation in the Plaintiff.

197. Defendant breached its duty by not performing life cycle testing on the HiRes 90k with an AstroSeal feed-thru before implantation in the Plaintiff.

198. As a direct and proximate result of Defendant's wrongful conduct, including failure to comply with applicable FDA requirements and FDA-approved Device specifications, Plaintiffs have sustained and will continue to sustain severe physical injuries, hearing loss, unnecessary surgery, severe emotional distress, economic losses and other damages for which they are entitled to compensatory damages in an amount to be proven at trial.

COUNT II

STRICT LIABILITY – DESIGN AND/OR MANUFACTURING DEFECT

199. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.

200. The Device was defectively designed and/or manufactured because the foreseeable risks of mechanical malfunction and failure using a device that leaks water outweighs the benefits associated with the device, particularly given that correct manufacturing technology allows medical device manufacturers to produce devices that do not leak to an excessive degree.

201. The devices were designed and/or manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.* (hereinafter "FDCA") and

applicable FDA regulations. The facilities or controls used by Defendant in the manufacture, packing, storage, or installation of the devices were not in conformity with applicable regulations and FDA-approved specifications for the device or the CGMP requirements set forth in FDA's quality system regulations, 21 C.F.R. Part 820.

202. The Device was expected to and did reach Logan without substantial change or adjustment to its mechanical function before implantation.

203. Defendant knew or should have known of the design and manufacturing defect and the risk of serious bodily injury that exceeded the benefits associated with the design of the Device.

204. Furthermore, the Device and its defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

205. The Device is inherently dangerous for its intended use due to design and/or manufacturing defect and improper functioning. Defendants are, therefore, strictly liable.

206. Defendant is in violation of the Tennessee Products Liability Act T.C.A., §§ 29-28-101 *et seq.*

207. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, hearing loss, unnecessary surgery, severe emotional distress, economic losses, and other damages for which they are entitled to recover in an amount to be proven at trial.

208. Defendant is liable to Plaintiffs for all general, special, and equitable relief to which Plaintiffs are entitled by law.

COUNT III

STRICT LIABILITY – FAILURE TO WARN

209. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.

210. At all relevant times hereto, Advanced Bionics was engaged in the development, testing, manufacturing, marketing and sales of the Device. Advanced Bionics designed, manufactured, assembled and sold the Device to medical professionals and their patients, knowing that they would then be implanted in patients with severe or profound hearing loss.

211. Advanced Bionics distributed and sold the Device in the condition in which it left their place of manufacture, in their original form of manufacture, which included the defects described herein. The Device was expected to and did reach Logan without substantial change in its condition as manufactured and sold by Defendant. At no time did Plaintiffs have reason to believe that the Device was in a condition not suitable for the Device's proper and intended use among the patients in whom the Devices were to be implanted.

212. The Device designed, developed, tested, manufactured, marketed, and sold or otherwise placed into the stream of commerce by Advanced Bionics was in a dangerous and defective condition and posed a threat to any user or consumer of the devices.

213. Plaintiffs were and are in a class of persons that Advanced Bionics should have considered to be subject to the harm caused by the defective nature of the Device.

214. The Device was implanted and used in the manner for which it was intended, that is, to provide hearing through surgical implantation. This use has resulted in injury to Plaintiff.

215. Plaintiffs were not able to discover, nor could they have discovered through the exercise of reasonable care, the defective nature of the Device. Further, in no way could Plaintiff

have known that Advanced Bionics had designed, developed, and manufactured the Device in such a way as to increase the risk of harm, injury or death to the recipients of the Device.

216. The Device was defective due to inadequate warnings or instruction because Defendants knew or should have known that the Device created a high risk of bodily injury and serious harm, that the Device was not hermetically sealed, that the Device was suffering a failure rate (sometimes referred to as a cumulative survival rate or “CSR”) in excess of what had been represented to the medical profession and the public, and that the Device was far less reliable than cochlear implants manufactured by its competitors. Defendants failed to adequately and timely warn consumers of this risk.

217. Defendant is in violation of the Tennessee Products Liability Act, T.C.A. §§ 29-28-101 *et seq.*

218. As a direct and proximate result of Advanced Bionics’ wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial. Advanced Bionics is liable to Plaintiffs for all general, special, and equitable relief to which Plaintiffs are entitled by law.

COUNT IV
NEGLIGENCE PER SE

219. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiffs’ Complaint as if fully set forth herein.

220. Defendant has an obligation not to violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, distribution, advertising, preparing for use, warning of the risks and dangers of the Device.

221. Defendant was negligent in the following ways:
- a. Advanced Bionics deviated from the FDA-approved design and manufacturing specifications for the HiRes 90k by, among other things, using a feed-thru component manufactured by AstroSeal rather than a feed-thru component manufactured by PA&E, including the violations described in the 2004 and 2005 FDA Form-483s and 2007 FDA Amended Complaint;
 - b. Advanced Bionics failed to obtain supplemental PMA approval for use of the AstroSeal feed-thru component through a 180-Day PMA Supplement or 30-Day Notice under 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. Part 814.39, including to the violations described in the 2004 and 2005 FDA Form-483s and 2007 FDA Amended Complaint;
 - c. Advanced Bionics failed to comply with the conditions of approval specified in the FDA PMA approving the HiRes 90k and earlier PMAs including, without limitation, the requirement that Advanced Bionics obtain supplemental approval prior to making any change that could affect the safety and effectiveness of a device;
 - d. Advanced Bionics failed to comply with applicable CGMPs in the manufacture of the HiRes 90k including, but not limited to, the violations described in the 2004/2005 FDA Form 483s, 2005 FDA Warning Letter; and the 2007 FDA Amended Complaint;
 - e. Advanced Bionics failed to comply with applicable adverse event reporting requirements involving the HiRes 90k, including, but not limited to, the violations

described in the 2005 FDA Warning Letter; and the 2007 FDA Amended Complaint;

- f. Advanced Bionics failed to ensure that HiRes 90k devices contained no more than 0.500% (5,000 ppm) moisture as required by its PMA;
- g. Advanced Bionics failed to sufficiently evaluate and select AstroSeal as a supplier of feed-thru assemblies on the basis of its ability to meet specified device requirements as required by the FDA CGMPs;
- h. Advanced Bionics failed to adequately validate the HiRes 90k devices by testing production lots under actual or simulated use conditions.

222. Defendant's acts constitute an adulteration, misbranding, or both, as defined by the Federal FDCA, 21 U.S.C. §§ 331(a) and 333(a)(2) and applicable FDA regulations, and constitute a breach of duty subjecting Defendant to civil liability for all damages arising therefrom and from parallel state law requirements, under the theory of negligence per se.

223. Plaintiffs, as purchasers of the Defendant's Device, is within the class of persons the statutes and regulations described above are designed to protect, and Plaintiffs' injuries are the type of harm these statutes and regulations are designed to prevent.

224. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendant is liable to Plaintiffs for all general, special, and equitable relief to which Plaintiffs are entitled by law.

COUNT V
BREACH OF EXPRESS WARRANTY

225. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.

226. Advanced Bionics by its acts and those of their agents expressly warranted to Plaintiffs that it was safe to use the Device.

227. Advanced Bionics offers a "10-year warranty on all Advanced Bionics cochlear implants."

228. Based on the allegations set forth in detail in this Complaint, Advanced Bionics violated T.C.A. § 47-2-313.

229. As a direct and proximate result of Advanced Bionics' breach of such express warranty, Plaintiffs suffered injuries and damages.

230. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendant is liable to Plaintiffs for all general, special, and equitable relief to which Plaintiffs are entitled by law.

COUNT VI
BREACH OF IMPLIED WARRANTY

231. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.

232. Advanced Bionics impliedly warranted that its Device, which Advanced Bionics designed, manufactured, assembled, promoted and sold to Plaintiffs, was merchantable and fit and safe for ordinary use. Advanced Bionics further impliedly warranted that their Device, which Advanced Bionics designed, manufactured, assembled, promoted and sold to Plaintiff, was fit for their particular purposes.

233. As a result of a manufacturing defect and violations of applicable CGMP requirements, Advanced Bionics' Device was defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which they were sold, and subjected Plaintiff to severe and permanent injuries and death.

234. Advanced Bionics breached the implied warranties of merchantability and fitness for a particular purpose when their Device was sold to Plaintiff, in that the Device is defective and has suffered water leaks and, therefore, failed to function.

235. Any disclaimers of implied warranties are ineffectual as they were not provided to Plaintiffs or otherwise made known to Plaintiffs. In addition, any such disclaimers are unconscionable.

236. Any purported written warranty fails of its essential purpose. Therefore, Defendant violated T.C.A. §§ 47-2-314, 315.

237. As a direct and proximate result of Advanced Bionics' breach of implied warranties, Plaintiffs have sustained economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial. Any disclaimer of consequential damages is invalid as the limited remedy provided fails in its essential purpose to redress the harm and personal injury to Plaintiffs in that it, in effect, provides

no remedy at all for the defect necessary to be redressed. In addition, any such disclaimer of consequential damages is unconscionable.

EIGHTH CAUSE OF ACTION

COMMON LAW FRAUD

238. Plaintiffs repeat, reallege and incorporate herein by this reference all of the preceding allegations as though set forth in full.

239. Advanced Bionics expressly, impliedly, falsely and fraudulently represented to members of the general public, including Plaintiffs and Logan's health care providers, that the HiRes 90k devices were of merchantable quality, in compliance with federal law and regulations, not adulterated, and safe for the use for which they were intended. These misrepresentations and omissions of fact include, but in no way limited to:

- a. Advanced Bionics never disclosed to Plaintiffs or Logan's physicians that it did not supplement its PMA Application to include the AstroSeal feed-thru.
- b. Advanced Bionics never disclosed to Plaintiffs or Logan's physicians that it did not test the HiRes 90k device in a simulated environment in which the device was to be prior to implantation in Logan.
- c. Advanced Bionics never disclosed to Plaintiffs or Logan's physicians that there was a history of moisture problems in the HiRes 90k or Clarion II/Clarion 1.2 devices prior to the date when Logan was implanted.
- d. Advanced Bionics never disclosed to Plaintiffs or their physicians that there was a history of device failures related to moisture with the Clarion and Clarion II Advanced Bionics cochlear implant devices.

- e. Advanced Bionics made representations via comments to Plaintiffs and/or Logan's physicians through oral representations and/or written promotional and marketing materials that its products were the most technologically advanced and the safest.

240. Advanced Bionics knowingly or recklessly made material false representations to Plaintiffs and Logan's healthcare providers about the functionality of his HiRes 90k device with the intent that he would act and/or refrain from acting on its representations.

241. Plaintiffs and Logan's health care providers relied upon said representations of Advanced Bionics in the selection, purchase, and use of the HiRes 90k device, and but for the falseness of those representations, implantation would not have occurred and/or Logan's defective device would have been removed much earlier.

242. Said representations by Advanced Bionics were false and untrue, in that the HiRes 90k devices were not in compliance with federal safety regulations and laws, were adulterated, were not safe for their intended use, nor were they of merchantable quality or functional devices as represented by Advanced Bionics. Advanced Bionics was aware that the devices had very dangerous properties and defects that could potentially cause injury and damage to the users of the HiRes 90k devices, including Logan, thereby threatening the health, life, and hearing of Logan.

243. At all times relevant to this action, prior to and at the time Advanced Bionics sold the devices and while they were surgically implanted, Advanced Bionics knew, as a result of complaints of other users, explant tests, research and other information, that the HiRes 90k devices, and their component parts, were defectively designed and/or manufactured, adulterated, and in violation of federal safety regulations and laws in that they had extremely dangerous

properties and defects. Advanced Bionics further knew that the devices had a propensity to stop functioning properly and/or completely fail, while implanted, from exposure to moisture and from other causes.

244. At all times relevant to this action, Advanced Bionics, despite the actual knowledge described herein above, intentionally suppressed the aforementioned test results, complaints, and other information to keep such knowledge from the general public, including Logan and his health care providers.

245. As a result of Advanced Bionics' conduct and Logan's detrimental reliance on the same, Plaintiffs have sustained and will continue to sustain physical injuries, emotional distress, economic losses and other damages for which they are entitled to damages.

COUNT VII
DECEPTIVE, UNFAIR, FRAUDULENT, AND/OR TORTIOUS
BUSINESS PRACTICES/THE TENNESSEE CONSUMER
PROTECTION ACT

246. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.

247. Advanced Bionics willfully and knowingly engaged in false advertising and other acts or practices that were deceptive, unfair, fraudulent, and/or tortious in the conduct of its business, trade, or commerce or in the furnishing of its services in contravention of The Tennessee Consumer Protection Act, T.C.A. 47-18-101, *et seq.*

248. Advanced Bionics misrepresented material facts to Plaintiffs, including but in no way limited to:

- a. Advanced Bionics never disclosed to Plaintiffs or Logan's physicians that it did not supplement its PMA Application to include the AstroSeal feed-thru.

- b. Advanced Bionics never disclosed to Plaintiffs or Logan's physicians that it did not test the HiRes 90k device in a simulated environment in which the device was to be prior to implantation in Logan.
- c. Advanced Bionics never disclosed to Plaintiffs or Logan's physicians that there was a history of moisture problems in the HiRes 90k or Clarion II/Clarion 1.2 devices prior to the date when Logan was implanted.
- d. Advanced Bionics never disclosed to Plaintiffs or their physicians that there was a history of device failures related to moisture with the Clarion and Clarion II Advanced Bionics cochlear implant devices.
- e. Advanced Bionics made representations via comments to Plaintiffs and/or Logan's physicians through oral representations and/or written promotional and marketing materials that its products were the most technologically advanced and the safest.

249. As a result of Defendant's aforementioned violative conduct, Plaintiffs were deceived and lured under false pretenses into undergoing the implantation of the Device.

250. As a result of Defendant's aforementioned violative conduct, Plaintiffs have suffered – and will continue to suffer – personal injuries and physical pain, as well as severe emotional and mental harm. In addition, Plaintiffs have sustained – and will continue to sustain – expenses for medical and/or surgical care that would have been unnecessary but for Defendant's aforementioned violative conduct.

251. Defendant had a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the Device.

252. Had Defendant not engaged in the deceptive conduct described above, Plaintiffs would not have agreed to the implantation of the Device into their son's head, and would not have incurred related medical costs.

253. Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed below.

254. Defendant engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiffs for the Device for which she would not have paid had Defendant not engaged in unfair and deceptive conduct.

255. Defendant's actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of the Tennessee Consumer Protection Act, T.C.A. § 47-18-101 *et seq.*

256. The cumulative effect of Defendant's conduct directed at patients, physicians and consumers was to create demand for and sell the Device. Each aspect of Defendant's conduct combined to artificially create sales of the Device.

257. The medical community relied upon Defendant's misrepresentations and omissions in determining which cochlear implant to utilize.

258. By reason of the unlawful acts engaged in by Defendant, Plaintiffs have suffered ascertainable loss and damages.

259. As a direct and proximate result of Defendant's violations of the consumer protection statute, Plaintiffs have sustained economic losses and other damages for which they are entitled to statutory, compensatory damages and declaratory relief in an amount to be proven

at trial. Defendant is liable to Plaintiffs for all general, special and injunctive relief to which Plaintiffs are entitled by law, and attorneys' fees, costs and interest.

COUNT VIII

NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

260. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.

261. Defendant carelessly and negligently designed, manufactured, marketed, and sold the Device to Plaintiffs, carelessly and negligently concealed the defects in the Device from Plaintiffs, and carelessly and negligently misrepresented the quality, safety, and usefulness of the Device. Defendant should have realized that such conduct involved an unreasonable risk of causing emotional distress to reasonable persons that might, in turn, result in illness or bodily harm.

261. Defendant owed a duty to treating physicians, recipients of the Device, and families of the recipients, including Plaintiffs, to accurately and truthfully represent the risks of the Device. Defendant breached that duty by misrepresenting and/or failing to adequately warn of the risks of the Device – effects of which Defendant knew or in the exercise of diligence should have known – to the treating physicians and Plaintiffs.

262. As a direct and proximate result of Defendant's wrongful conduct and breach of duty, Plaintiffs have sustained and will continue to sustain severe emotional distress either due to physical injury or a rational fear of physical injury or death and is entitled to recovery of damages in an amount to be proven at trial. Defendant is liable to Plaintiffs for all general, special and equitable relief to which Plaintiffs are entitled by law.

COUNT IX

INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

263. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.

264. Defendant's conduct directed toward Plaintiffs' minor son, was, by act and omission, intentional, knowing, and/or reckless, and evidenced a willful intention to inflict injury upon Plaintiff's minor son, or a reckless disregard for the rights and interests of Plaintiffs' minor son equivalent to an intentional violation of them. This conduct exceeded all bounds usually tolerated by decent and civilized society and was directed toward an inherently vulnerable population of persons with profound hearing loss.

265. As a direct, proximate, intended, known, natural, and foreseeable result of Defendant's conduct, Plaintiffs and their minor son was and is suffering injury in the form of serious, severe, extreme and/or disabling emotional distress that no reasonable person could or should be expected to endure.

266. Defendant is liable and accountable at law to compensate Plaintiffs and their minor son for such emotional distress, and for all such damages and injuries resulting therefrom and related thereto.

267. Defendant's conduct was intentional, knowing, oppressive, fraudulent, malicious, extreme and outrageous, and done in conscious and reckless disregard of Plaintiffs and their minor son's rights, thereby entitling Plaintiffs to seek to assert claims for exemplary and punitive damages, at the appropriate time under governing law, in an amount sufficient, necessary and appropriate to punish Defendant for its reprehensible conduct and to deter it and others from such conduct in the future. Defendant is liable to Plaintiffs for all general, special and equitable relief to which Plaintiffs are entitled by law.

COUNT X
PUNITIVE DAMAGES

268. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.

269. The wrongs done by Defendant were aggravated by malice, fraud, and reckless disregard for the rights of others, the public, and Plaintiffs and their son.

270. Defendant was actually, subjectively aware of the risk involved in continuing to market the Device despite having failed to ensure that the Device was hermetically sealed and free of excessive moisture, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of patients, including Logan.

271. Plaintiff asserts claims for exemplary and punitive damages in an amount allowed pursuant to the policy enunciated in Hodges vs. S.C. Toof and Company, 833 S.W. 2d 896 (Tenn. 1992) in an amount that would punish Defendant for its conduct and which would deter other manufacturers from engaging in such misconduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendant as follows:

- A. For compensatory damages in the sum of \$3,000,000.00;
- B. For punitive damages against Defendant Advanced Bionics consistent with the degree of Defendant's reprehensibility and the resulting harm or potential harm to Plaintiffs and their minor child in an amount of \$5,000,000.00.
- C. For all applicable statutory damages under consumer protection legislation;
- D. For prejudgment interest and the costs and expenses of suit; and
- E. For such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a jury trial on all issues so triable.

Respectfully submitted,

**GLASSMAN, EDWARDS, WADE
& WYATT, P.C.**

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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was forwarded by either U.S. Mail, e-mail, or electronic means via the Court's electronic filing system to:

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this 20th day of April, 2010.

/s/ Edwin E. Wallis III _____.