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

| | | |
|---|---|---|
| WYLY WADE individually and as next friend of K.W., a minor, on behalf of himself, K.W., and all others similarly situated, | ) | |
| Plaintiff, | ) | |
| vs. | ) | No. 12-cv-2877 |
| COCHLEAR LIMITED, an Australian public company, | ) | |
| | ) | **JURY TRIAL DEMANDED** |
| Defendant. | ) | |

## CLASS ACTION COMPLAINT

Plaintiff, Wyly Wade, individually and as next friend of K.W., a minor, on behalf of himself, K.W., and all others similarly situated, complaining against Defendant, Cochlear Limited, an Australian public company, states as follows:

## Nature of Action

1. Plaintiff, Wyly Wade, individually and as next friend of K.W., a minor, on behalf of himself, K.W., and all others similarly situated, brings this class action on behalf of himself, K.W., and all others similarly situated. Plaintiff and the putative class of United States citizens received implants of the Nucleus CI500 range of cochlear implant medical devices manufactured by Defendant Cochlear Limited ("Cochlear" or "Defendant"). Cochlear Nucleus CI500 range cochlear implant medical devices manufactured by Defendant (the "Cochlear Implants" or the "Recalled Devices") were recently subject to a global recall. Cochlear recalled the Cochlear Implants through an announcement issued in September 2011, which indicated that the Cochlear Implants had experienced an increased failure rate.

2. The safety and efficacy of the Cochlear Implants are the focal point of this lawsuit. Plaintiff alleges that Cochlear exposed K.W. and all putative Class Members to the risk of device failure, corrective surgery and personal injury, among other things. Plaintiff's claims are predicated on Cochlear's violations of federal law.

## Parties

3. Plaintiff, Wyly Wade, individually and as next friend of K.W., a minor, is a United States citizen domiciled in Cook County, Illinois.

4. K.W., a minor, is a United States citizen and the minor daughter of Wyly Wade.

5. Cochlear is an Australian public company with its principal place of business in New South Wales, Australia. Cochlear holds itself out as "The leading global hearing solutions company."

6. At all times relevant, Cochlear was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, obtaining regulatory approval for, and introducing into interstate commerce throughout the United States, either directly or indirectly through third parties or related entities (including its wholly-owned U.S. subsidiary Cochlear Americas, a Delaware corporation) numerous cochlear implant medical devices, including the Recalled Devices at issue.

## Jurisdiction and Venue

7. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332(a) because there is complete diversity of citizenship between Plaintiff and Defendant, and the amount in controversy, exclusive of interest and costs, exceeds $75,000. Further, this Court has jurisdiction over this action pursuant to 28 U.S.C. §1332(d), because the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, and is a class action in

which any member of a class of plaintiffs is a citizen of a state different from any defendant. Finally, this Court has jurisdiction pursuant to 28 U.S.C. §1331 because Plaintiff's claims arise under the laws of the United States, including the Federal Food, Drug, and Cosmetic Act, as more fully set forth below.

8. Venue is proper in this district pursuant to 28 U.S.C. §1391(c)(3), because Cochlear, as an Australian public company not resident in the United States may be sued in any judicial district.

## FACTUAL BACKGROUND

### The Cochlear Implants

9. The 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.

10. The Cochlear Implants' system contains both internal and external components.

11. The Cochlear Implants' system's external components include a sound processor and magnetic coil that are worn behind the ear.

12. The Cochlear Implants' system's internal 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 under the skin behind the ear, and into the cochlea (inner ear).

13. The Cochlear Implants' internal receiver/stimulator contains a feedthrough assembly to allow for contact between the internal electrical components and the external components.

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

**The Cochlear Implants' Failure and Recall**

15. On or about September 14, 2011, the Australian government issued an urgent medical device recall and hazard alert in connection with the Recalled Devices, reference number RC-2011-RN-00920-3.

16. The products recalled in this Australian governmental recall under the Cochlear Nucleus CI500 Implant Range were the: CI512 cochlear implant with contour advance electrode (Part Number: Z209051), Australian Register of Therapeutic Goods (ARTG) 165361; CI513 cochlear implant with contour advance electrode (Part Number: Z110048), ARTG 165362; ABI541 Auditory Brainstem Implant (Part Number: Z246605); and CI551 Double Array (Part Number: Z246605).

17. The stated reason for the Australian governmental recall was that it followed a recent increase in the number of failures of CI512 cochlear implants in the Cochlear Nucleus CI500 range. According to the recall, the information available to the Australian government's Therapeutic Goods Administration was that less than 1% of the recalled implants had failed. The recall was considered a safety related recall.

18. On or about September 16, 2011 Defendant's wholly-owned American subsidiary, Cochlear Americas, sent an "URGENT MEDICAL DEVICE RECALL" letter to all 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. A recall response form was attached to the letter for customers to complete and return.

19. On or about October 3, 2011 the United States Food and Drug Administration ("FDA") issued a Class 2 Recall, pursuant to Recall Number Z-0003-2012, for the Cochlear Nucleus CI512 Cochlear Implant, REF Z209051, New with Nucleus 5, Sterile EO.

20. According to the FDA's October 3, 2011 recall, the Recalled Devices were intended to restore a level of auditory sensation via the electrical stimulation of the auditory nerve.

21. According to the FDA's recall, the reason for the recall was that the Recalled Devices may shut down and cease to function.

22. According to the FDA's recall, there was worldwide distribution of the Recalled Devices, including nationwide distribution in the United States.

23. On or about December 16, 2011, Defendant's CEO and president, Dr. Chris Roberts, released a letter advising that:

> "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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24. On or about February 6, 2012 Defendant's CEO and president, Dr. Chris Roberts, released a letter 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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25. Upon information and belief, at least 25,516 Recalled Devices have been implanted into putative Class Members' bodies.

## Facts Regarding Plaintiff

26. K.W., Plaintiff' minor daughter, was deaf in both ears.

27. As a toddler, K.W. was medically evaluated for cochlear implants and determined to be an excellent candidate to receive cochlear implants.

28. On or about June 3, 2011, both of K.W.'s ears were surgically implanted with the Cochlear Implants manufactured by Defendant.

29. The Cochlear Implants were implanted in every putative Class Member utilizing the same general procedure.

30. In or about August 2011, the Cochlear Implant in K.W.'s right ear failed.

31. In or about September 2011, the Cochlear Implant in K.W.'s left ear failed.

32. Upon information and belief, K.W.'s Cochlear Implants failed due to an electronic failure resulting from a loss of hermeticity (i.e. failure of the moisture impervious seal) of the titanium chassis of each of the Cochlear Implants' respective internal receivers/stimulators.

33. Upon information and belief, this loss of hermeticity in each of K.W.'s Cochlear Implants' internal receivers/stimulators resulted from unintended variations in the brazing process during Defendant's manufacturing of K.W.'s Cochlear Implants.

34. Upon information and belief, brazing is the process that joined the feedthrough of K.W.'s Cochlear Implants to their respective titanium chassis.

35. Upon information and belief, these unintended variations in Defendant's brazing process resulted in K.W.'s Cochlear Implants being more susceptible to developing microcracks in the braze joint during Defendant's subsequent manufacturing steps.

36. Upon information and belief, microcracks developed in each of the braze joints of K.W.'s Cochlear Implants during Defendant's manufacturing process.

37. Upon information and belief, these microcracks in the braze joints of K.W.'s Cochlear Implants allowed water molecules to enter each of K.W.'s Cochlear Implants and cause a malfunction of certain electronic components contained in each of K.W.'s Cochlear Implants.

38. Upon information and belief, Defendant failed to detect these microcracks in K.W.'s Cochlear Implants' braze joints during Defendant's manufacturing process related testing.

39. Upon information and belief, these microcracks in each of K.W.'s Cochlear Implants' braze joints existed at the time that K.W.'s Cochlear Implants left the hands of Defendant.

40. On or about September 28, 2011, K.W.'s Cochlear Implants were surgically explanted from both of K.W.'s ears due to their electronic failure resulting from the loss of hermeticity.

**Federal Requirements**

41. The Recalled Devices are Class III medical devices regulated by the FDA.

42. 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.

43. A medical device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, 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.

44. Medical device manufacturers such as Defendant are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices.

45. In particular, medical device manufacturers such as Defendant must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury.

46. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device, such as Defendant, to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. § 360i.

47. 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).

48. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR § 820 et seq. As explained in the Federal Register, because Current Good Manufacturing Practice ("CGMP") regulations apply to a variety of medical devices, the regulations do not prescribe the exact details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of minimum requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing processes employed. Manufacturers must adopt current

and effective methods and procedures for each device they design and manufacture to comply with and implement the minimum requirements set forth in the quality system regulations.

49. 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).

50. Pursuant to 21 CFR§ 820.5, each manufacturer of a medical device, such as Defendant, shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. See 21 CFR §820.3(v).

51. Pursuant to 21 CFR§ 820.22, each manufacturer of a medical device, such as Defendant, shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

52. Pursuant to 21 CFR §820.30(a), each manufacturer of a medical device, such as Defendant, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

53. Pursuant to 21 CFR § 820.30(d), each manufacturer of a medical device, such as Defendant, shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

54. Pursuant to 21 CFR § 820.30(e), each manufacturer of a medical device, such as Defendant, shall establish and maintain procedures to ensure that formal documented reviews of

the design results are planned and conducted at appropriate stages of the device's design development.

55. Pursuant to 21 CFR § 820.30(f), each manufacturer of a medical device, such as Defendant, shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

56. Pursuant to 21 CFR § 820.30(g), each manufacturer of a medical device, such as Defendant, 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.

57. Pursuant to 21 CFR § 820.30(h), each manufacturer of a medical device, such as Defendant, shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

58. Pursuant to 21 CFR §820.30(i), each manufacturer of a medical device, such as Defendant, shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

59. Pursuant to 21 CFR §820.70(a), each manufacturer of a medical device, such as Defendant, shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process

control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

a. Documented instructions, standard operating procedures ("SOP"'s), and methods that define and control the manner of production;

b. Monitoring and control of process parameters and component and device characteristics during production;

c. Compliance with specified reference standards or codes;

d. The approval of processes and process equipment; and;

e. Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

60. Pursuant to 21 CFR §820.70(b), each manufacturer of a medical device, such as Defendant, shall establish and maintain procedures for changes to a specification, method, process, or procedure.

61. Pursuant to 21 CFR § 820.70(c), each manufacturer of a medical device, such as Defendant, shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

62. Pursuant to 21 CFR § 820.70(e), each manufacturer of a medical device, such as Defendant, shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

63. Pursuant to 21 CFR § 820.70(g), each manufacturer of a medical device, such as Defendant, shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

64. Pursuant to 21 CFR § 820.70(h), each manufacturer of a medical device, such as Defendant, shall establish and maintain procedures for the use 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 device's quality.

65. Pursuant to 21 CFR § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the medical device manufacturer, such as Defendant, shall validate computer software for its intended use according to an established protocol.

66. Pursuant to 21 CFR § 820.72, each manufacturer of a medical device, such as Defendant, shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained.

67. Pursuant to 21 CFR § 820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. 21 CFR § 820.3(z)(1).

68. Pursuant to 21 CFR § 820.75(b), each manufacturer of a medical device, such as Defendant, shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

69. Pursuant to 21 CFR § 820.90, each manufacturer of a medical device, such as Defendant, shall establish and maintain procedures to control product that does not conform to specified requirements.

70. Pursuant to 21 CFR § 820.100, each manufacturer of a medical device, such as Defendant, shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems;

b. Investigating the cause of nonconformities relating to product, processes, and the quality system;

c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished devices;

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

g. Submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

71. Upon information and belief, the Recalled Devices have experienced an unintended loss of hermeticity.

72. Upon information and belief, the Recalled Devices' loss of hermeticity has resulted from unintended variations in the brazing process during Defendant's manufacturing of the Recalled Devices.

73. Upon information and belief, brazing is the process that joins the Recalled Devices' feedthrough to the receiver/stimulator's titanium chassis.

74. Upon information and belief, these unintended variations in Defendant's brazing process have resulted in the Recalled Devices being more susceptible to developing microcracks in the braze joint during Defendant's subsequent manufacturing steps.

75. Upon information and belief, these microcracks in the braze joint allow water molecules to enter the Recalled Devices and cause a malfunction of certain electronic components contained therein.

76. Upon information and belief, these microcracks in the Recalled Devices' braze joint developed during Defendant's manufacturing process.

77. Upon information and belief, Defendant failed to detect these microcracks in the Recalled Devices' braze joint during Defendant's manufacturing process related testing.

78. Upon information and belief, these microcracks in the Recalled Devices' braze joint existed at the time that the Recalled Devices left the hands of Defendant.

79. Upon information and belief, the Recalled Devices are adulterated pursuant to 21 U.S.C. §351 because, among other things, they failed to meet established performance standards, and/or the methods, facilities, or controls used for their manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. §351.

80. Upon information and belief, the Recalled Devices are misbranded because, among other things, they are dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. §352.

81. Upon information and belief, the Recalled Devices are adulterated pursuant to 21 U.S.C. § 351 because Defendant failed, among other things, to establish and maintain CGMP for its Recalled Devices in accordance with 21 CFR §820 et seq., as set forth above.

82. Upon information and belief, Defendant failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for the Recalled Devices.

83. As a result of Defendant's failure to establish and maintain CGMP as set forth above, the Recalled Devices were defective and failed, resulting in injuries to Plaintiff as well as all putative Class Members.

84. If Defendant had complied with the federal requirements regarding CGMP, the Recalled Devices would have been manufactured properly such that they would not have resulted in injuries to Plaintiff or the putative Class Members.

## Class Allegations

85. Plaintiff seeks to bring this civil action as a class action, under Federal Rule of Civil Procedure 23(a), (b)(1) & (b)(3), on behalf of himself, K.W. and all others similarly situated as members of the proposed Classes ("Class Members"), defined as follows:

a. All United States citizens who received a Nucleus CI500 range cochlear implant medical device manufactured by Defendant;

b. All United States citizens and entities that paid for the implantation of a Nucleus CI500 range cochlear implant medical device manufactured by Defendant; and

c. All United State citizens and entities that paid for the explantation of a Nucleus CI500 range cochlear implant medical device manufactured by Defendant.

## Rule 23(a) Requirements

86. The Class Members are so numerous that joinder of all members is impracticable. Further, the Class Members who received the Recalled Devices are expected to number in the thousands.

87. Common questions of law and fact affect the rights of each Class Member, and, among other things, a common remedy of medical monitoring is sought for the Class Members.

88. Common questions of law and fact that affect the Class Members include but are not limited to:

a. Whether Defendant violated federal law in the design and/or manufacture of the Recalled Devices;

b. Whether the Recalled Devices are defective in design or manufacture;

c. Whether Defendant knew or should have known of the defects in the Recalled Devices prior to their sale and surgical implantation into Class Members;

d. Whether Defendant delayed in recalling the Recalled Devices and failed to provide timely and adequate post-market warning or instruction of the health risk created by the Recalled Devices; and

e. Whether medical monitoring must be provided for recipients of the Recalled Devices, and what monitoring is necessary.

89. The claims and defenses of Plaintiff, as the representative Plaintiff, are typical of the claims and defenses of the class.

90. Plaintiff, as the representative Plaintiff, will fairly and adequately assert and protect the interests of the class:

a. Plaintiff has hired Attorneys who are experienced in prosecuting class action and complex litigation claims and will adequately represent the interests of the Class; and

b. Plaintiff has no conflict of interest that will interfere with the maintenance of this Class Action.

**Rule 23(b) Requirements**

91. The prosecution of separate actions by or against individual Class Members would create risk of inconsistent or varying adjudications with respect to individual Class Members which would establish incompatible standards of conduct for the party opposing the Class, or adjudications with respect to individual Class Members which would, as a practical matter, be dispositive of the interests of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests, rendering class certification appropriate under Rule 23(b)(1).

92. Specifically, Plaintiff seeks, among other things, medical monitoring as a remedy on behalf of persons who have received the Recalled Devices.

93. In order to create a medical monitoring program that provides each Class Member with access to care and that enables Defendant to administer a uniform program as a remedy to the class, certification under Rule 23(b)(1) is necessary. Without such a certification, Class Members who no longer have health insurance, or who have inadequate finances to advance the costs, or whose doctors do not agree to perform the necessary tests, or who have limited access to facilities, would not be assured of obtaining the necessary diagnostic and monitoring procedures.

94. Questions of law or fact common to the members of the Class predominate over questions affecting only individual members, and a class action is superior to other available methods for the fair and efficient adjudication of the controversy.

95. Specifically, while each Class Member who received a Recalled Device may suffer harm due to the implantation of the Recalled Device, these unique medical issues pertain primarily to damages. The common issues include Defendant's violations of federal law resulting in the defect found in the Recalled Device received by Class Members, Defendant's knowledge of the defect, and Defendant's failure to issue an adequate and timely post-market recall. These central factual and liability issues common to the Class Members predominate over individual issues of damages, rendering class certification appropriate under Rule 23(b)(3). These facts and issues would be key and central in each and every individual case if tried separately.

96. Further, in order to obtain relief in a single forum to all affected claimants, a Class Action is a superior procedural method that will enable the class to obtain comprehensive relief

for all Class Members. By individualizing the determination of damages for Class Members, any concerns regarding control of individual litigation will be protected and addressed.

**FIRST CAUSE OF ACTION:**
**STRICT PRODUCTS LIABILITY- DEFECTIVE MANUFACTURING**

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

98. Defendant is the designer, manufacturer, distributor, seller, and/or supplier of the Recalled Devices.

99. The Recalled Devices that Defendant designed, manufactured, sold, distributed, supplied and/or placed in the stream of commerce were defective in their manufacture, construction, or composition when they left the hands of Defendant in that they deviated in a material way from Defendant's approved product specifications, Defendant's approved manufacturing performance standards, and/or other applicable federal requirements for the Recalled Devices, posing a serious risk of medical device failure and associated medical treatment, including surgical procedures to remove the Recalled Devices and replace them with non-defective cochlear implant medical devices.

100. As a direct and proximate result of Plaintiff's and Class Members' use of Defendant's Recalled Devices as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant and/or Defendant's failure to comply with federal law, Plaintiff and Class Members suffered serious physical injury, harm, damages, economic loss and will continue to suffer such harm, damages, and economic loss in the future.

101. Defendant's acts and 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

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

103. Defendant is the designer, manufacturer, distributor, seller, and/or supplier of the Recalled Devices.

104. The Recalled Devices, as manufactured and supplied by Defendant, were defective in design or formulation in that, when they left the hands of Defendant, the foreseeable risks of harm posed by the Recalled Devices exceeded the benefits associated with the design or formulation, and the Recalled Devices were more dangerous than an ordinary consumer would expect, because they failed to comply with federal requirements for these medical devices.

105. The foreseeable risks associated with the design or formulation of the Recalled Devices, include, but are not limited to, the fact that the design or formulation of the Recalled Devices 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.

106. As a direct and proximate result of Plaintiff's and Class Members' use of the Recalled Devices, as designed, manufactured, sold, supplied, marketed and introduced into the stream of commerce by Defendant and/or Defendant's failure to comply with federal requirements, Plaintiff and the Class Members suffered serious physical injury, harm, damages, economic loss and will continue to suffer such harm, damages and economic loss in the future.

107. Defendant's 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**

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

109. Defendant is the designer, manufacturer, distributor, seller, and/or supplier of the Recalled Devices.

110. The Recalled Devices, as manufactured and supplied by Defendant, were defective in that, when they left the hands of Defendant, they did not conform to representations made by Defendant concerning the product and they failed to comply with applicable federal requirements.

111. Plaintiff and Class Members and/or their physicians justifiably relied upon Defendant's representations regarding the Recalled Devices when they selected the Recalled Devices to be used in surgery.

112. As a direct and proximate result of Plaintiff's and Class Members' use of the Recalled Devices, and Plaintiff's and Class Members' reliance on Defendant's representations regarding the character and quality of the Recalled Devices and Defendant's failure to comply with federal requirements, Plaintiff and Class Members suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

113. Defendant's 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

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

115. Defendant researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Recalled Devices, and in the course of the same directly advertised or marketed the product to health care professionals and consumers, including Plaintiff and Class Members, or persons responsible for Plaintiff and Class Members, and therefore had a duty to warn of the risks associated with the use of the Recalled Devices.

116. Defendant failed to adequately warn health care professionals and the public, including Plaintiff and Class Members, including their prescribing physician, of the true risks of the Recalled Devices, including the propensity to fail, causing pain and suffering and requiring further treatment, including surgery.

117. Defendant failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Recalled Devices. Had it done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician and Class Members' physicians would have implanted the Recalled Devices.

118. The Recalled Devices were defective due to inadequate post-marketing warnings regarding the increased risk of failure resulting in pain and suffering and the need for surgery, while knowing that a safer alternative design existed.

119. Defendant 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.

120. As a direct and proximate result of the conduct of the Defendant, Plaintiff and Class Members suffered or will suffer serious and permanent non-economic and economic injuries.

121. Defendant's conduct, as described above, was reckless. Defendant risked the lives and health of consumers and users of the Recalled Devices, including Plaintiff and Class Members with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendant made a conscious decision not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendant's 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**

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

123. Defendant had a duty to exercise ordinary care in the design, formulation, testing, quality assurance, quality control, labeling, manufacture, marketing, promotion, sale and/or distribution of the Recalled Devices into the stream of commerce, including both a duty to assure that the Recalled Devices did not pose a significantly increased risk of bodily harm and adverse events, and a duty to comply with federal requirements.

124. Defendant failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of the Recalled Devices into interstate commerce in that Defendant knew or should have known that the Recalled Devices had a propensity to fail and cause bodily harm and were not safe for use by consumers, because Defendant failed to comply with federal requirements.

125. Defendant had a duty to exercise ordinary care in the advertising and sale of the Recalled Devices, including a duty to warn Plaintiff and Class Members of the dangers associated with the Recalled Devices that were known or should have been known to Defendant at the time of sale to Plaintiff and Class Members.

126. Defendant failed to exercise ordinary care in the advertising and sale of the Recalled Devices by failing to warn Plaintiff and Class Members of the dangers associated with the Recalled Devices that were known or should have been known to Defendant at the time of sale to Plaintiff and to Class Members. Defendant failed to warn Plaintiff or Class Members that the Recalled Devices had a propensity to fail, cause bodily harm and require surgical replacement.

127. Defendant had a duty to exercise ordinary care in the labeling of the Recalled Devices and failed to issue adequate pre-marketing or post-marketing warnings to doctors, Plaintiff, Class Members or the general public, regarding the propensity of the Recalled Devices to fail, cause bodily harm and require surgical replacement.

128. Defendant failed to exercise ordinary care in the labeling of the Recalled Devices and failed to issue adequate pre-marketing or post-marketing warnings to doctors, Plaintiff, Class Members or the general public, regarding the propensity of the Recalled Devices to fail, cause bodily harm and require surgical replacement.

129. Despite the fact that Defendant knew or should have known that the Recalled Devices posed a serious risk of bodily harm to consumers, Defendant continued to manufacture and market the Recalled Devices for use by consumers and continued to fail to comply with federal requirements.

130. Defendant knew or should have known that consumers such as Plaintiff and Class Members would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

131. Defendant breached its duty of ordinary care to Plaintiff and Class Members by failing to exercise due care under the circumstances as follows:

a. Failing to use due care in the development, design, formulation, manufacturing, labeling, testing, assembly, marketing, advertising, promotion, inspection, sale and/or distribution of the Recalled Devices, and/or to utilize and/or implement reasonably safe designs for them;

b. Failing to provide adequate and proper warnings to the public, Plaintiff, and/or Class Members of the dangerous propensities of the Recalled Devices when used in a reasonably foreseeable manner;

c. Failing to conduct adequate post-marketing surveillance;

d. Failing to design, formulate, manufacture and incorporate or to reformulate the Recalled Devices with reasonable safeguards and protections against the type of injury and damage suffered by Plaintiff and Class Members when used in a reasonably foreseeable manner;

e. Failing to adequately prevent, identify, mitigate and fix defective designs and hazards associated with the Recalled Devices in accordance with good design practices;

f. Failing to notify and warn the public including Plaintiff and Class Members of reported incidents of failure, necessitating surgery, personal injury attendant to the failure, thus misrepresenting the safety of the Recalled Devices;

g. Failing to make timely and adequate corrections to the manufacture, design and formulation of the Recalled Devices so as to prevent and/or minimize the problems encountered by Plaintiff and Class Members as a result of their use of the Recalled Devices;

h. Failing to use due care in the testing, formulation, inspection, distribution, sale and instructions regarding the product at all times prior to Plaintiff's and Class Members' injuries having manifested themselves;

i. Continuing to promote and market the device despite its knowledge of these risks; and

j. Being otherwise careless, reckless and negligent.

132. As a direct and proximate result of Defendant's acts and omissions, Plaintiff and Class Members had the Recalled Devices surgically implanted and have 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.

133. Defendant's conduct as described herein was reckless. Defendant risked the lives and health of Plaintiff and Class Members through the use of the Recalled Devices with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Upon information and belief, Defendant made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendant's 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:
## BREACH OF EXPRESS WARRANTY

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

135. Defendant expressly warranted that the Recalled Devices were a safe and effective hearing device for those patients requiring a hearing device.

136. At the time of making the express warranties, Defendant had knowledge of the purpose for which the Recalled Devices were to be used and warranted the same to be, in all respects, fit, safe, effective, and proper for such purpose.

137. Plaintiff and Class Members reasonably relied upon the claimed skill and judgment of Defendant, the self-designated "Leading global hearing solutions company," and upon said express warranty, in electing to have the Recalled Devices surgically implanted.

138. The Recalled Devices manufactured and sold by Defendant did not conform to these express representations because they caused serious injury to Plaintiff and Class Members when used as recommended and directed.

139. Defendant violated 21 U.S.C. §331(a) by introducing and delivering adulterated and misbranded medical devices into interstate commerce.

140. As a direct and proximate result of Defendant's breach of warranty, Plaintiff and Class Members have suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

## SEVENTH CAUSE OF ACTION:
## BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

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

142. At the time Defendant designed, manufactured, marketed, sold, and distributed the Recalled Devices for use by Plaintiff and Class Members, Defendant knew of the use for which the Recalled Devices were intended and impliedly warranted the Recalled Devices to be of merchantable quality and safe for such use and that its design, manufacture, labeling, and marketing complied with all applicable federal requirements.

143. Plaintiff and Class Members and/or their physicians reasonably relied upon the skill and judgment of Defendant as to whether the Recalled Devices were of merchantable quality and safe for the intended use and upon Defendant's implied warranty as to such matters, including that they complied with all federal requirements.

144. Contrary to such implied warranty, Defendant's Recalled Devices were not of merchantable quality or safe for their intended use, because the products were defective as described above, and failed to comply with federal requirements.

145. As a direct and proximate result of Defendant's breach of warranty, Plaintiff and Class Members have 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:
## NEGLIGENT MISREPRESENTATION

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

147. In the exercise of ordinary care, Defendant knew or should have known that the Recalled Devices failed to comply with federal requirements for safe design and manufacture and/or were in other ways out of specification, yet Defendant negligently misrepresented to Plaintiff and Class Members and/or their physicians that the Recalled Devices were safe and met all applicable design and manufacturing requirements.

148. Plaintiff and Class Members and/or their physicians reasonably relied to their detriment upon Defendant's misrepresentations and omissions in its labeling, advertisements, and promotions concerning the serious risks posed by these products.

149. Plaintiff and Class Members and/or their physicians reasonably relied upon Defendant's representations that the Recalled Devices were safe for use.

150. As a direct and proximate result of Defendant's negligent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to the Recalled Devices, Plaintiff and Class Members used Defendant's Recalled Devices and Plaintiffs and Class Members have 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:
## MEDICAL MONITORING CLASS MEMBERS

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

152. As a direct result of Defendant's actions and/or omissions, the defective Recalled Devices were implanted in Plaintiff's and Class Members' skulls.

153. Plaintiff and Class Members seek medical monitoring as a remedy.

154. Medical monitoring procedures sought by Plaintiff and Class Members includes monitoring the performance of the Recalled Devices and other monitoring procedures deemed necessary, all to be performed on a recommended schedule.

155. Accordingly, Defendant should be required to establish a medical monitoring program that includes, *inter alia*:

a. Establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of all recipients of Defendant's Recalled Devices, as frequently as determined to be medically necessary; and

b. Notifying Plaintiff, Class Members, and their physicians, that their Recalled Device require frequent medical monitoring.

156. Plaintiff and Class Members have no adequate remedy at law, in that monetary damages alone cannot compensate them for the risk of future serious and permanent physical injury. Without a Court-approved medical monitoring program as described herein, Plaintiff and Class Members will continue to face an unreasonable risk of serious and permanent physical injury.

**TENTH CAUSE OF ACTION:**
**CONSTRUCTIVE TRUST**

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

158. Defendant profited monetarily from its wrongful and unconscionable conduct, using artifice, concealment and questionable acts. Those profits may not in equity and good conscience be held and enjoyed by Defendant.

159. Defendant’s monetary profits should be impressed with a constructive trust and held by Defendant in constructive trust for the benefit of Plaintiff and Class Members who have inequitably borne the health care costs related to the Recalled Devices caused by Defendant’s conduct.

160. Plaintiff and Class Members are therefore entitled to compensation from Defendant for past and future damages, including but not limited to, health care expenditures related to the Recalled Devices, together with interest and costs.

161. Plaintiff and Class Members are entitled to the imposition of a constructive trust against Defendant for the benefit of Plaintiff and Class Members in the amount of money expended to purchase the Recalled Devices, implant the Recalled Devices, explant the Recalled Device, or that may be expended in the future for the same.

**ELEVENTH CAUSE OF ACTION:**
**UNJUST ENRICHMENT**

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

163. As an intended and expected result of its conscious wrongdoing as set forth herein, Defendant has profited and benefited from payments Plaintiff and Class Members made for the Recalled Devices, payments made for surgical explantation of the Recalled Devices, and payments Plaintiff and Class Members made for purchase and surgical implantation of replacement hearing aid devices.

164. In exchange for the payments made for the Recalled Devices, and at the time payments were made, Plaintiff and Class Members expected that the Recalled Devices were safe and medically effective for the condition for which they were prescribed.

165. Defendant voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of its wrongdoing, Plaintiff and Class Members paid for the Recalled Devices when they otherwise would not have done so.

166. Defendant's failure to provide Plaintiff or Class Members with the renumeration expected unjustly enriched the Defendant.

167. Plaintiff and Class Members are entitled in equity to seek restitution of Defendant's wrongful profits, revenues, and benefits to the extent and in the amount deemed

appropriate by the Court and such other relief as the Court deems just and proper to remedy the Defendant's unjust enrichment.

WHEREFORE, Plaintiff and Class Members request judgment against Defendant Cochlear Limited, an Australian public company, as follows:

a. Certifying this action to be a class action pursuant to Rule 23(a), (b)(1) & (b)(3) of the Federal Rules of Civil Procedure, and appointing the named Plaintiff as proper class representative of the class;

b. Awarding Plaintiff and Class Members compensatory damages in excess of the minimal jurisdiction amount for this Court, as well as punitive damages as a result of the wrongs alleged herein;

c. Imposing a constructive trust against Defendant for the benefit of Plaintiff and Class Members;

d. Establishing a medical monitoring program for the benefit of Plaintiff and Class Members;

e. Entering an injunction prohibiting Defendant from communicating with Plaintiff and Class Members concerning this civil action through Plaintiff's and Class Members' respective health care professionals;

f. Granting Plaintiff and Class Members a trial by jury pursuant to Federal Rule of Civil Procedure 38(b) on all issues so triable;

g. Awarding reasonable attorney's fees and costs;

h. Awarding prejudgment and post-judgment interest;

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

Respectfully submitted,

WYLY WADE, INDIVIDUALLY AND AS NEXT FRIEND OF K.W., A MINOR, ON BEHALF OF HIMSELF, K.W., AND ALL OTHERS SIMILARLY SITUATED

By: /s/ Scott A. Morgan

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