

UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the matter of

Advanced Bionics, LLC,  
12740 San Fernando Road  
Sylmar, California

and

Jeffrey H. Greiner, an individual,

Respondents.

FDA Docket: 2007H-0433

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**ANSWER OF RESPONDENT ADVANCED BIONICS LLC**

Pursuant to 21 C.F.R. § 17.9 (2007), Respondent, Advanced Bionics, LLC (“Bionics” or “Respondent”), hereby answers the Amended Administrative Complaint for Civil Penalties (“Amended Complaint”), and requests a hearing.

**INTRODUCTION**

This case is about a material that, according to the laws of physics, does not and cannot exist. The scientific facts that will develop in this case will seem bizarre, but even FDA concedes that they are true.

Somehow, one of Advanced Bionics’ vendors, referred to in the Amended Complaint as “Vendor B,” created a material that is totally impervious to tiny helium molecules and totally impervious to nitrogen molecules, but allows much larger water molecules to leak through. Bionics has now spent two years and millions of dollars trying to understand this physics-defying

*FDA-2007-H-0094*

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phenomenon. Although various theories have been proposed, there is no scientifically accepted explanation of what it is happening. Yet, it is happening. The existence of this scientific anomaly is undisputed.

Despite the bizarre nature of this failure mechanism, FDA seeks to impose millions of dollars of penalties on Bionics and one of its two co-CEOs on the ground that Bionics should have anticipated such a scientific anomaly.

In fact, Bionics' most persuasive expert-witness evidence about the apparent physical impossibility of what is happening will come from FDA, itself. It is a widely known scientific principle universally relied upon in the implantable-medical-device industry, and by FDA, that, if helium cannot penetrate a material (such as, for example, Bionics' Vendor- B-feedthru assembly or any other hermetic case), then water cannot. In August 2004, some of FDA's best scientific experts inspected Bionics for two weeks and during that time carefully reviewed data from devices that had been explanted from patients. Those explanted devices showed no gas leakage, but had high moisture, and that moisture caused the devices to fail. Because (FDA's experts confidently and logically concluded) it is impossible for a device to allow water to leak through but not to allow gas to leak through, the moisture inside the devices could not possibly have come from the patients' bodies. FDA's experts (again, confidently and logically) reasoned that, if the moisture inside the devices did not come from the patients' bodies, the only remaining scientifically possible explanation is that the moisture must have been sealed into the devices during Bionics' manufacturing process. The Form FDA-483 delivered by FDA investigators at the end of the August 2004 inspection concluded that Bionics' manufacturing process was sealing moisture into Bionics' devices, and that, as a result, medical devices that left the factory subject to premature failure. From this confident and apparently scientifically mandated

conclusion, the FDA-483 extrapolated 21 separate objectionable conditions in Bionics' quality system that were responsible for this supposed state of affairs. FDA's conclusions and science were logical and (despite Bionics' best efforts and understanding at the time) indisputable. Bionics concurred with FDA's conclusions. Those conclusions were also, it turns out, 100% wrong. Thus FDA's diagnosis in 2004, made in good faith and based on good science and common sense at the time, is now completely discredited. That fact also is undisputed.

Bionics is bewildered that this Agency, the same Agency whose best scientists concluded, in 2004, that moisture could not possibly be leaking into Bionics' devices, is seeking to impose civil monetary penalties on Bionics because (1) it was finally discovered, in 2006, that moisture was, in fact, leaking into Bionics' devices, and (2) Bionics did not know, in 2003, that the universally understood laws of physics appear not to apply to Vendor B's feedthrus.

#### **RESPONSES TO THE AMENDED COMPLAINT'S SPECIFIC ALLEGATIONS**

Respondent denies all allegations contained in headings or unnumbered paragraphs of the Amended Complaint. Respondent answers the allegations contained in the numbered paragraphs of the Amended Complaint as follows:

1. Paragraph 1 contains conclusions of law, as to which no response is required. To the extent a response is deemed necessary, Respondent is without knowledge or information sufficient to form a belief as to the truth of the allegation that this action is brought by FDA on behalf of CDRH, and Respondent admits the other allegations contained in paragraph 1.

2. Respondent admits that Bionics manufactures a cochlear implant, the HiRes90K Implantable Cochlear Stimulator ("HiRes90K" or "CII-x"), and that the previous version of the device was referred to as the CII. Otherwise, paragraph 2 contains conclusions of law, as to which no response is required. To the extent a response is deemed necessary, Respondent admits

that the HiRes90K is a class III device, for the distribution in commerce of which approval of a premarket approval application (“PMA”) is required.

3. Respondent admits the allegations of paragraph 3, except that in the fourth sentence the words “external components” should be replaced with the words “the electrode array and antenna coil.”

4. Respondent denies the allegations of paragraph 4, except that Respondent admits that the CII-x feedthru assembly contains a titanium case with 22 openings, that each opening has a platinum pin that serves as a separate electrical connection between the internal electronics and the electrode array and antenna coil (as applicable), and that each opening is filled with glass that bonds both with the titanium case and the platinum pin to create a seal that is specified to be hermetic to helium gas to at least  $10^{-9}$  per Military Standard 883.

5. Respondent admits that the HiRes90K is the latest in a series of models of cochlear implants manufactured by Bionics. Respondent admits that Bionics first received PMA approval to market cochlear implants for adult use in March 1996. Respondent admits that Bionics submitted a PMA supplement for a version of a cochlear implant device called the “HiRes90K,” and that FDA approved that PMA supplement on July 7, 2003. Respondent admits that the PMA supplement for the HiRes90K was the 30<sup>th</sup> PMA supplement submitted by Bionics for its cochlear implant devices. Respondent admits that, with each supplement approval, FDA included the statement: “Before making any change affecting safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA . . . .”

6. Respondent admits that, in April 2001, FDA conducted an inspection of Bionics and that, at the end of that inspection, FDA found no objectionable conditions and listed no observations on an FDA-483. Respondent admits that, in December 2001, FDA conducted

another inspection of Bionics, and that, at the end of that inspection, FDA issued an FDA-483 listing six observations. Respondent admits that five of the observations related to medical device reports and did not mention PMA requirements, and that one observation stated: "Failure to submit PMA supplements for the following testing, manufacturing process and design changes: A. Implementation of the gross leak test on or about April 1, 2001. B. Implementation of the modified fixture for the vacuum bake on or about December 2000. C. Implementation of the helium bomb leak test on or about February 1, 1999. D. Increasing the zirconia case wall thickness (CIM4) on or about January 1, 1999." Respondent admits that the FDA-483 was given to Mr. Greiner, and that the Establishment Inspection Report ("EIR") prepared by FDA following the inspection states that certain observations, excluding the observation related to PMA supplements, were discussed with him. Respondent is without sufficient information to admit or deny the remaining allegations in paragraph 6, and therefore denies them.

7. Respondent admits the allegations in paragraph 7.

8. Respondent admits that, for over two years before FDA approved the PMA supplement relating to the CII-x in July 2003, Bionics had used two vendors—Vendor B and another vendor referred to as "Vendor A"—to make feedthru assemblies for Bionics' CII cochlear implants. Respondent also admits that, after receiving FDA's approval of the CII-x, Bionics continued using both vendors to make feedthru assemblies—now for the CII-x. Respondent admits that Respondent's Vice President for Regulatory Affairs sent a letter to FDA, on April 28, 2007—almost four years after receiving PMA supplement approval for the CII-x—describing differences between the two feedthrus. Respondent denies the allegations in paragraph 8 insofar as they suggest that the use of Vendor B feedthrus represented a change in

design or specification requiring a filing of a PMA supplement, and Respondent denies all remaining allegations in paragraph 8.

9. Respondent denies the allegations in paragraph 9 insofar as they suggest that the use of Vendor B as a vendor of feedthru assemblies in the CII-x represented a change from Bionics' manufacturing practice with respect to the CII. Respondent denies the allegations in paragraph 9 insofar as they suggest that the use of Vendor B as a vendor of feedthru assemblies in the CII-x required any filings with the FDA. Respondent denies all other allegations in paragraph 9.

10. Respondent admits that FDA conducted an inspection of Bionics' facilities from August 25 through September 15, 2004. Respondent admits that, at the conclusion of this inspection, FDA issued a Form FDA-483 to Bionics and that this FDA-483 listed 23 observations—all but 2 of which related to the now-completely-discredited-diagnosis of entrapped moisture. Respondent denies that any observation made by FDA in the FDA-483 issued at the conclusion of the 2004 inspection relates to the violations alleged in the Amended Complaint. Respondent admits that excessive moisture in the CII-x devices can cause those devices to fail prematurely, and that, if a device implanted in a patient does fail, the patient must undergo surgery to explant the failed device and reimplant a new device. Respondent admits that, in late 2004, Bionics initiated a voluntary recall of all unimplanted cochlear implants, including both CII-x and CII versions based on the now-completely-discredited diagnosis of entrapped moisture. Respondent denies the remaining allegations contained in paragraph 10.

11. Respondent admits that, on or about February 1, 2005, it received from FDA a Warning Letter addressed to Mr. Greiner. Respondent admits that this Warning Letter contained allegations of deviations from FDA regulations set forth in 21 C.F.R. Part 820, which were based

on the now-completely-discredited diagnosis of entrapped moisture. Respondent admits that Bionics responded to the Warning Letter in a letter dated February 18, 2005 signed by Mr. Greiner. Respondent denies that the Warning Letter related in any way to any of the allegations in the Amended Complaint. Respondent denies all other allegations of paragraph 11.

12. Respondent admits that Bionics voluntarily recalled HiRes90K devices containing feedthru assemblies from Vendor B on March 8, 2006. Respondent is without knowledge and information sufficient to form a belief as to the truth of the allegation that a telephone call took place between the Vice President of Regulatory Affairs for Bionics and FDA on March 15, 2006, and, if such a call took place, what was said, and therefore denies the same. Respondent denies all other allegations of paragraph 12.

13. Respondent admits that two HiRes90K devices containing Vendor B feedthrus were shipped by Bionics after the recall was initiated because the shipping employees did not know that the devices contained Vendor B feedthrus. Respondent admits that those two unknowingly shipped devices were later implanted in patients. Respondent denies that it failed to adequately notify facilities consistent with its obligations in executing the Class 2 recall in March 2006. Respondent admits that, in March, 2006, there were approximately 4041 devices with feedthrus from Vendor B that were implanted, and that of these 1797 were implanted in pediatric patients. Respondent denies the remaining allegations of paragraph 13.

14. Respondent admits the allegations in the first sentence of paragraph 14. Respondent admits that, during that inspection, FDA investigators discussed with Bionics the company's use of Vendor B as a vendor for the feedthru assembly. Respondent is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 14 and therefore denies them.

15. Respondent does not know what "FDA learned," and therefore is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first sentence of paragraph 15, and therefore denies the same. Respondent admits that, for the CII-x, Respondent used Vendor B as a supplier of feedthrus, and that the qualification tests did not include a hydrostatic test or corrosion test. Respondent denies the allegations in paragraph 15 insofar as they suggest that the use of feedthrus from Vendor B represented a change in design or specification for which the filing of a PMA supplement was required, and Respondent denies all other allegations in paragraph 15.

16. Paragraph 16 contains legal conclusions, to which no response is required. To the extent a response is required, Respondent admits that the statutes cited in paragraph 16 speak for themselves; and Respondent denies all other allegations in the paragraph.

17. Respondent admits the allegations of paragraph 17, except that Respondent is a limited liability company—not a corporation.

18. Respondent admits that, at all relevant times, Jeffrey H. Greiner was President and Co-Chief Executive Officer of Bionics and, together with Alfred Mann, shared overall executive responsibility and authority over Bionics' operations, including the manufacturing, labeling, promoting, holding, selling, and distribution of devices at 12740 San Fernando Road. Respondent denies the remaining allegations of paragraph 18.

19. Paragraph 19 contains legal conclusions, to which no response is required. To the extent a response is required, Respondent admits that the statutes and regulations cited in paragraph 19 speak for themselves; and Respondent denies all other allegations in the paragraph.

20. Paragraph 20 contains legal conclusions, to which no response is required. To the extent a response is required, Respondent admits that the regulations cited in paragraph 20 speak for themselves; and Respondent denies all other allegations in the paragraph.

21. Paragraph 21 contains legal conclusions, to which no response is required. To the extent a response is required, Respondent admits that the statutes and regulations cited in paragraph 21 speak for themselves; and Respondent denies all other allegations in the paragraph.

22. Paragraph 22 contains legal conclusions, to which no response is required. To the extent a response is required, Respondent admits that the regulation cited in paragraph 22 speaks for itself; and Respondent denies all other allegations in the paragraph.

23. Paragraph 23 contains legal conclusions, to which no response is required. To the extent a response is required, Respondent admits that the regulation cited in paragraph 23 speaks for itself; and Respondent denies all other allegations in the paragraph.

24. Paragraph 24 contains legal conclusions, to which no response is required. To the extent a response is required, Respondent admits that the regulations cited in paragraph 24 speak for themselves; and Respondent denies all other allegations in the paragraph.

25. Paragraph 25 contains legal conclusions, to which no response is required. To the extent a response is required, Respondent admits that the statute cited in paragraph 25 speaks for itself; and Respondent denies all other allegations in the paragraph.

26. Paragraph 26 contains legal conclusions, to which no response is required. To the extent a response is required, Respondent admits that the statutes cited in paragraph 26 speak for themselves; and Respondent denies all other allegations in the paragraph.

27. Paragraph 27 contains legal conclusions, to which no response is required. To the extent a response is required, Respondent admits that the statutes and regulations cited in paragraph 27 speak for themselves; and Respondent denies all other allegations in the paragraph.

28. Paragraph 28 contains legal conclusions, to which no response is required. To the extent a response is required, Respondent denies the allegations of paragraph 28, including without limitation the allegations in subparagraphs (a) and (b)(i) through (b)(iii).

29. Paragraph 29 contains legal conclusions, to which no response is required. To the extent a response is required, Respondent denies the allegations in paragraph 29.

30. The first sentence of paragraph 30 contains legal conclusions, to which no response is required. To the extent a response is required, Respondent denies the allegations of that sentence. Respondent admits that devices using feedthru assemblies supplied by Vendor B have an explant rate substantially greater than that of devices using feedthru assemblies supplied by Vendor A, and that the precise comparison between these two explant rates depends upon the date as of which the comparison is made (paragraph 30 contains no date reference).

31. Respondent denies the allegations of paragraph 31. Respondent admits that it shipped more than 74 devices that contained feedthrus from Vendor B in the period from July 2003 to March 2006. Respondent admits that its shipping personnel unknowingly shipped two devices that contained feedthrus from Vendor B after those devices had been recalled in March 2006.

32. Paragraph 32 contains legal conclusions, to which no response is required. To the extent a response is required, Respondent admits that FDA is seeking civil monetary penalties from Respondent and Mr. Greiner in the amount of \$1.1 million each. Respondent denies that it

or Mr. Greiner has committed any violation alleged in the Amended Complaint for which Respondent or Mr. Greiner is liable for civil monetary penalties.

33. Paragraph 33 contains legal conclusions, to which no response is required. To the extent a response is required Respondent admits that the regulations cited in paragraph 33 speak for themselves; and Respondent denies all other allegations in the paragraph.

### DEFENSES

Pursuant to 21 C.F.R. § 17.9(b)(2), Respondent lists below defenses on which it currently intends to rely. As contemplated by 21 C.F.R. § 17.9(d), Respondent reserves the right to amend this Answer, including amending these defenses and/or adding additional defenses, as this case proceeds.

1. In FDA's December 2001 inspection of Bionics, FDA cited Bionics in an FDA-483 for failure to submit PMA supplements. When FDA re-inspected Bionics in 2002, FDA verified as corrected the observations from the December 2001 inspection—including the observation regarding failure to file PMA supplements. Thus, Bionics and Mr. Greiner did not fail to correct the matters stated in the 2001 Form FDA-483 and did not fail to make the changes needed. To the contrary, they promptly and completely fulfilled the commitments to FDA that arose out of the December 2001 inspection, and FDA confirmed in writing their having done so.

2. Complainant is barred from asserting any claim because, with respect to the change to Respondent's cochlear implant device that turned the excellent-reliability CII device with feedthrus from Vendor B into the less-reliable CII-x device with feedthrus from Vendor B, Respondent submitted a PMA supplement to FDA that identified the change that mattered to safety (embedding the feedthru assembly in silicone instead of epoxy), and FDA approved that change when it approved Respondent's PMA supplement. That is, the critical difference between the reliability of the CII devices with feedthru assemblies from Vendor B and the CII-x

devices with feedthru assemblies from Vendor B—the difference, which was unknown at the time but emerged later, between the excellent reliability of the CII and the lower reliability of the CII-x—was the change from embedding the feedthru assembly in epoxy (in the CII) to embedding it in silicone (in the CII-x). This change affected the reliability of only the devices with feedthru assemblies from Vendor B due to latent characteristics of the Vendor B component (these characteristics did not affect the reliability of that component in the CII device, and did not become apparent during Bionics’ rigorous, industry-standard testing described elsewhere herein). FDA did not require, for its approval of the CII-x supplement, any testing of the CII-x that would have revealed the physics-defying characteristics of the Vendor B feedthrus.

3. For over two years before FDA approved the PMA supplement relating to the CII-x in July 2003, Bionics had used two vendors—Vendor B and another vendor, referred to in the Amended Complaint as “Vendor A”—to make feedthru assemblies for Bionics’ predecessor cochlear implant, the CII. The CII cochlear implants incorporating feedthrus from both vendors were highly reliable. Thus, good science and common sense supported Bionics’ belief in 2003 that (a) Vendor B’s feedthrus was every bit as good as Vendor A’s feedthrus, and (b) Vendor B’s feedthrus would be highly reliable in the CII-x.

4. Although, in the samples tested to provide data for Respondent’s PMA supplement for the CII-x, feedthrus from Vendor A were used, Bionics did not specify whether feedthrus from one or both manufacturers would be used in the CII-x. FDA’s approval of the PMA supplement did not specify, or explicitly or implicitly incorporate by reference a specification, that only Vendor-A feedthrus could be used.

5. After receiving FDA’s approval of the CII-x, Bionics continued using both vendors to make feedthru assemblies—now for both the CII and the CII-x. The feedthru

assemblies from both vendors had the same design specification: both feedthru assemblies were required to be hermetic to helium gas to at least  $10^{-9}$  per Military Standard 883. All feedthru assemblies from both vendors were tested to this exacting industry standard for helium-leak rates multiple times during the manufacturing process, and all feedthru assemblies from both vendors were required to pass, and did pass, this test before being released as final product, either in the CII or CII-x version of Bionics' cochlear implant. In these circumstances, Bionics did not consider that the continued use of the feedthrus from Vendor B, now in the CII-x, constituted any "change" under 21 C.F.R. § 314.39 for which a PMA supplement or a statement in a periodic report was required.

6. Under FDA's guidance document, Modifications To Devices Subject to Premarket Approval – The PMA Supplement Decision Making Process (1998) (the "1998 Guidance"), the circumstances surrounding Respondent's use of feedthru assemblies from Vendor B did not trigger a requirement to file a PMA supplement. Likewise, under the 1998 Guidance, the circumstances did not trigger a requirement to file any other notice with FDA, including notice in an annual or other periodic report.

7. Respondent applied "good science and common sense" in reaching its decision regarding submission of a PMA supplement in connection with the use of feedthru assemblies from Vendor B in the CII-x, in compliance with the standard set forth by FDA in the preamble to the final PMA regulation,. *See* 51 Fed. Reg. 26,353 (July 22, 1986). Bionics had successfully used Vendor B as a vendor of feedthru assemblies for over two years in its CII device. All feedthrus from Vendor B used in manufacturing Bionics' devices passed an exacting, industry-standard helium-leak test. In the CII-x, these devices failed to be reliable in patients because of a physics-defying phenomenon that is inexplicable even two years after it was discovered—not

because Bionics failed to use good science or common sense, and not because Bionics failed to use manufacturing practices that complied with 21 C.F.R. Part 820. Indeed, Respondent's decision-making process, lack of FDA filings, and requirement that each feedthru be helium-leak tested as it used feedthru assemblies from Vendor B in the CII-x version of its cochlear implant in 2003 was substantially identical to Respondent's decision-making process, lack of FDA filings, and requirement that each feedthru be helium-leak tested as it used feedthru assemblies from Vendor B in the CII version of Bionics' cochlear implant. As to each device, Bionics' conduct was lawful.

8. As demonstrated by FDA's own good science and common sense in connection with the 2004 inspection, in the state of scientific knowledge before March 2006, it was good science and common sense for Bionics to believe that the helium-leak test per Military Standard 883 was fully adequate to determine whether moisture could leak into the feedthru assemblies Respondent obtained from Vendor B. On that basis, it was good science and common sense for Bionics to believe that it was impossible for there to be a material difference in performance between feedthru assemblies from Vendor B and feedthru assemblies from Vendor A with respect to the imperviousness of the feedthru assemblies to moisture. Indeed, in the state of scientific knowledge and industry testing standards at that time, it would have been unreasonable for Respondent to believe that there was such a performance difference between the two feedthrus, and it was impossible using industry-standard leak testing for Respondent's manufacturing process to detect such a performance difference.

9. The Amended Complaint's allegations of violation of good-manufacturing-practice ("GMP") requirements under the Quality System Regulation, 21 C.F.R. Part 820, depend entirely on the belief that, if Respondent had done the same full-device-level testing on

devices made with Vendor B's feedthrus as Respondent had done on devices used for the CII-x PMA supplement, then the Vendor B problem would have been discovered before devices were implanted in patients. That belief is not correct. Even if Bionics had done full-device-level testing on devices made with Vendor B feedthrus, there is virtually no chance that Vendor B's physics-defying characteristics would have been discovered.

10. Because in 2003 and until 2006, no one, neither Bionics nor FDA, could imagine a material that could consistently and repeatedly pass a helium-leak test, and yet not be hermetic, FDA's approval of the CII-x PMA supplement did not require any test that would have identified the bizarre physics-defying problem associated with feedthru assemblies from Vendor B. Because even the testing to the level of a PMA supplement would not have discovered the Vendor B problem, the alleged failure to file a PMA supplement and the alleged failures to qualify Vendor B as a supplier and the alleged failure to adequately test feedthrus, was not the cause of any harm to patients.

11. In 2004, Respondent's outside expert on preventing moisture in its devices disputed FDA's theory of entrapped moisture, on the basis of the overall effectiveness of Respondent's procedures for drying out devices during manufacture, but could not propose any logical or scientifically plausible explanation for how moisture could leak into the devices without the devices also allowing gas to leak in. Nevertheless, it is now absolutely clear that FDA's theory of entrapped moisture, which was good science and common sense in 2004, was completely wrong. If FDA's experts could not discover this physics-defying phenomenon in the Fall of 2004, Bionics could not have discovered it in the Summer of 2003.

12. FDA had at least three opportunities to formally state its view that Bionics should have filed a PMA supplement regarding use of the Vendor B feedthru in the CII-x:

(1) Respondent has documentary evidence that, during FDA's 2004 inspection, at 3:42 p.m. on August 25, Respondent told FDA that it was using two suppliers of feedthru assemblies. No observation was made in the FDA-483 that Bionics should have filed a PMA supplement for use of Vendor B feedthrus in the CII-x.

(2) When Bionics recalled all CII-x devices with Vendor B feedthrus in March 2006, FDA did not cite Bionics for failing to file a PMA supplement for use of Vendor B feedthrus in the CII-x.

(3) Perhaps most significantly, during the 2007 inspection, which FDA admits was focused on the March 2006 recall of Vendor B devices, the investigators only discussed whether Bionics should have filed a PMA supplement for use of Vendor B feedthrus in the CII-x. No observation was included on the FDA-483 relating to failure to file a PMA supplement.

The Amended Complaint's description of the 2007 inspection is important because FDA's Investigations Operations Manual ("IOM"), which FDA describes as "the primary source regarding Agency policy and procedures for field investigators and inspectors," (*see* IOM, Foreword, available at [http://www.fda.gov/ora/inspect\\_ref/iom/IOMForeword.html](http://www.fda.gov/ora/inspect_ref/iom/IOMForeword.html)), contains the following statement:

All FDA-483s should adhere to the following general principles:

1. Observations which are listed should be significant and correlate to regulated products or processes being inspected.
2. Observations of *questionable significance* should not be listed on the FDA-483, but will be discussed with the firm's management so that they understand how uncorrected problems *could become* a violation. This discussion will be detailed in the EIR.

IOM, § 5.2.3 (available at [http://www.fda.gov/ora/inspect\\_ref/iom/ChapterText/5\\_2.html#5.2.3](http://www.fda.gov/ora/inspect_ref/iom/ChapterText/5_2.html#5.2.3))

(emphasis added). FDA's citation of Respondent for violations of 21 C.F.R. Part 814 is contrary

to the IOM. The Amended Complaint's allegation of violations of 21 C.F.R. Part 814 are contrary to the policy set forth in the IOM. FDA has not provided Respondent the EIR for the 2007 inspection.

13. The Amended Complaint is barred by principles of equitable estoppel and/or laches.

14. The Amended Complaint fails to state a claim upon which relief can be granted.

15. The Amended Complaint is not supported by the facts.

16. Respondent complied with all applicable laws and regulations, including FDA's PMA regulation, 21 C.F.R. Part 814, and FDA's Quality System Regulation, 21 C.F.R. Part 820.

17. Respondent did not violate the Quality System Regulation because that regulation does not require that a manufacturing process detect, or be able to detect, a condition in a device that appears, from available scientific knowledge, to be impossible.

18. Respondent incorporates herein paragraphs 1-12 of these Defenses. If, and to the extent that, Respondent violated any provision of the Federal Food, Drug, and Cosmetic Act or any provision of FDA's regulations, it was objectively impossible for Respondent to comply.

19. Respondent incorporates herein paragraphs 1-12 of these Defenses. As applied to the facts of this case, the statutory provisions and regulations the Amended Complaint alleges Respondent violated are unconstitutionally vague and otherwise deny due process of law in violation of the Fifth Amendment to the Constitution of the United States.

20. Respondent's notifications to centers in connection with the 2006 recall complied with all applicable laws and regulations.

## PENALTIES

Pursuant to 21 C.F.R. § 17.9(b)(3) (2007), Respondent lists below reasons why any penalties assessed should be less than the requested amount. As contemplated by 21 C.F.R. § 17.9(d), Respondent reserves the right to amend this Answer, including amending these reasons and/or adding additional reasons, as this case proceeds.

1. With respect to the change to Respondent's cochlear implant device that turned the highly reliable CII device with Vendor B feedthru into the less reliable CII-x device with Vendor B feedthru, Respondent submitted a PMA supplement to FDA that identified the change (embedding the feedthru assembly in silicone instead of epoxy), and FDA approved that change when it approved Respondent's PMA supplement. Respondent did not seek to evade FDA jurisdiction.

2. With respect to the alleged GMP violations, Respondent received no prior warning from FDA regarding the regulatory violations alleged in the Amended Complaint. With respect to the prior FDA-483 observation with respect to non-filing of PMA supplements, Respondent promptly corrected the matter observed by FDA in December 2001, and, less than 12 months later, FDA verified, in writing, that Respondent had done so.

3. Respondent has no history of significant prior violations and, to the contrary, has a history of responding promptly and working cooperatively with FDA to address FDA's observations about Respondent's quality system. The only significant FDA compliance activity related to Respondent occurred in connection with FDA's 2004 inspection and a related warning letter—both of which were based on FDA's now-completely-discredited theory of entrapped moisture. Respondent made every reasonable effort in good faith to comply with the law.

4. Even though Respondent did not agree with the magnitude and severity of FDA's observations arising out of the 2004 inspection and warning letter, Respondent spent millions of

dollars destructively testing devices to prove that no moisture was entrapped during the manufacturing process, hundreds of thousands of dollars in outside consultant expenses and thousands of engineering hours trying to understand the physics-defying phenomenon of imperviousness-to-gas-but-not-to-moisture failure mode of feedthru assemblies from Vendor B theorized by FDA, and has increased spending on its quality system by over 500% from 2004 to present day. This work was done long before any administrative complaint was filed.

5. Respondent did not violate any clear FDA policy or regulation.

6. Respondent has consistently demonstrated a commitment to regulatory compliance, including by elevating, early in its history, the head of regulatory affairs to a Vice President level position.

7. Respondent has not engaged in (a) any flagrant or egregious violation, (b) any violation involving fraud or dishonesty, (c) any knowing or intentional violation, (d) any continuing or repeated violation after failing to take effective corrective action after prior notice or warning from FDA, or (e) any violation that reflected indifference to or reckless disregard for public health or safety.

8. Although Respondent deeply regrets the unknowing shipment of two devices with feedthrus from Vendor B after the March 2006 recall, this unknowing shipment did not reflect a general failure to have control over distribution. Rather, the shipment of these two recalled units resulted from a one-time human error. The employees involved have been retrained and procedures to prevent a recurrence were promptly and comprehensively implemented.

9. There is no precedent for imposition of a civil monetary penalty under 21 U.S.C. § 333 on a respondent so lacking in moral culpability, and the imposition here of the

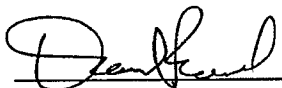
maximum legally permissible penalty, as requested in the Amended Complaint—or any substantial penalty—would be inequitable.

10. Respondent has never made any profit any time in its history.

11. As a result of the moisture problems in devices containing feedthrus from Vendor B, Respondent has already suffered a total financial loss exceeding \$20 million—not including lost revenues as a result of the Vendor B reliability issue.

12. Respondent incorporates by reference all defenses listed above.

Respectfully submitted,



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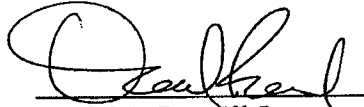
April 21, 2008

**CERTIFICATE OF SERVICE**

I hereby certify that the foregoing has been served by overnight mail and e-mail this 21st day of April 2008 to:

Jennifer E. Caruso  
U.S. Food and Drug Administration  
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Daniel L. Russell Jr.