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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District

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Irvine, California 92612-2506
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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 09-05

February 1, 2005

Jeffrey H. Greiner
President and Co-CEO
Advanced Bionics Corporation
12740 San Fernando Road
Sylmar, California 91342

Dear Mr. Greiner:

During an inspection of your establishment located in Sylmar, California, conducted from August 25 to September 15, 2004 our investigators determined that your firm manufactures cochlear implants which are designed to provide useful hearing to individuals with severe to profound hearing loss. Cochlear implants are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection disclosed that your devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage or installation are not in conformance with the Current Good Manufacturing Practice (cGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to conduct management reviews with sufficient frequency, as required by 21 CFR 820.20(c). Specifically, the last management review was conducted in March 2004. A significant manufacturing deficiency, moisture being hermetically sealed in the Hi Res 90K cochlear implant, has not been addressed in management reviews, although it was known that devices distributed with weld dates from August 2002, were suspect devices. Confirmatory evidence (residual gas analysis (RGA)) of moisture sealed in devices and produced from November 2002, through November 2003, was available from device failure analyses.

Review of RGA test results showed that the specification limit for moisture was exceeded and that residual helium, an indicator of hermeticity, may be present. Thus, this phenomenon (entrapped moisture) is not limited only to the HiRes 90K device. Moisture in ceramic housing devices were also noted without finding breach in hermeticity in some failure analysis reports dating back to 2002. Entrapped moisture in the firm's implants could result from several deficiencies, such as, process deficiencies in manufacturing, inadequate failure investigations, and overall quality system deficiencies.

In your response dated October 18, 2004, your firm states that you will update the Quality System Review Operating Procedure, OP 1.1.3, to change the requirement for management review meetings from annually to quarterly as well as add a requirement for monthly reliability reviews. Your response states that this OP would be released by October 29, 2004. Please provide us with a copy of the revised OP for evaluation. The adequacy and implementation of these changes will be verified during your next scheduled inspection.

2. Failure to establish procedures for conducting quality audits and to 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, as required by 21 CFR 820.22.

Specifically,

- (a) A review of the internal audit procedure and the 2004 Internal Audit Schedule lacked a requirement and/or details for auditing manufacturing processes and process validation of manufacturing processes. The audit procedure OP: 6.1.1 internal audit procedure requires the auditor to prepare an audit checklist in advance of the audit. There is no procedure on how this checklist is to be prepared or that the checklist was reviewed and approved prior to its use.

Your response states that your firm will revise the Internal Audit Operating Procedure, OP 6.1.1, to specify the review and approval of the audit checklist used by internal auditors which will be released by October 29, 2004. Your firm also states that the Process Control Audit would be completed in November 2004. Additionally, subject matter experts were to be added to the internal audit team and trained by December 17, 2004. Please provide a copy of the revised Internal Audit Procedure, OP 6.1.1, the data from the Process Control Audit, and documentation of the December 17, 2004, training for review. The adequacy and implementation of these changes will be verified during your next scheduled inspection.

- (b) A review of the 2004 Internal Audit Schedule does not indicate a scheduled audit for manufacturing processes and process validation of manufacturing processes. The failure analysis results provided indicators of potential processing problems with test results identifying residual moisture in hermetically sealed devices. There was no modification of 2004 Internal Audit Schedule to audit or re-audit management controls, design controls, CAPA, including corrective and preventive action procedures, failure investigation procedures, and PAPC including manufacturing production and process controls, process validations and others quality system requirements to identify potential deficiencies that could account for residual moisture in finished devices.

Your response states that Advanced Bionics will increase the technical expertise of the internal audit team by adding subject matter experts from R & D and Product Engineering and training these team members by December 17, 2004. Please provide documentation of this training for review. The training records will be verified during your next scheduled inspection.

- (c) A significant failure investigation finding of moisture being sealed within hermetically sealed devices was noted as early as May 2004, which spanned production from November 2002 to November 2003. Out of compliance devices had Residual Gas Analysis test results ranging from 1.15% to over 40% (200,000 PPM), in contrast to the specification of 0.50% (5,000 PPM).

In addition to finding moisture in the HiRes 90K devices, the problem of moisture in failed devices (Failed devices with no evidence of breach of seal have been identified in previous model cochlear implants.) For example,

Model 1.2 RGA	% Water	He	O	Tested
8496	32.91	13.55	0.17	10/2/03
1397	34.2	13.2	0.11	10/22/03
61366	29.07	14.6	0.13	2/1/02
6329	26.22	15.38	0.11	2/1/02
72757	32.94	15.15	0.13	3/5/04
8630	12.42	21.3	0.08	3/22/02

The presence of moisture potentially results in dendrite growth, corrosion, and ultimate failure of the device. Root cause of the moisture in hermetically sealed devices have not been identified; products continue to be manufactured and distributed, thus exposing patients to the risk of device failure and the associated risks of surgical intervention and potential permanent loss of hearing.

Review of failure analysis information for the HiRes 90k devices noted failure in the quality system to control moisture limits within the hermetically sealed cochlear implant devices. Two of the three vacuum bake ovens used for moisture removal have not been validated. Process controls are not effective in detecting gross leaks. Your devices have been distributed and implanted, only to fail due to an un-welded vent hole, a leaking vent hole and one device was determined to have been sealed in room air. There is a lack of in-process or finished device sampling and testing to determine if devices are conforming to moisture limits before devices are accepted and distributed.

Your response states that you have revised the Process Validation and Verification Procedure, OP 4.8.1, to comply with established validation guidelines and principles and are conducting an investigation into the CLARION® device failures that would be completed by November 30, 2004. You also state that Advanced Bionics will re-validate the vacuum bake process to ensure that the HiRes90K device meets the newly adopted residual moisture specification which will be completed by Q1 2005. Please provide the revised procedure for OP 4.8.1, and results of the investigation into the CLARION® device failures for review. The adequacy and implementation of these changes will be verified during your next scheduled inspection.

3. Failure to establish procedures for identifying training needs and to ensure that all personnel are trained to adequately perform their assigned responsibilities, as required 21 CFR 820.25(b).

Specifically,

- (a) There is inadequate knowledge regarding how residual gas analysis results can be used to determine if the device was hermetically sealed with water within the device at the time of manufacture or if the water entered the device as a result of a loss of hermeticity;
- (b) Inspection of process validation documents demonstrated that employees need training in the basic principles of process validation;
- (c) The firm was unable to provide a rationale for performing product or process risk analysis. The risk analysis documents did not take into account the risk associated with surgical

explants and replacement of defective devices. This observation indicates that the firm needs a training procedure to identify GMP deficiencies.

- (d) Established risk analysis and process validation procedures were not being followed. This observation indicates that the firm needs a training procedure to identify GMP deficiencies and training needs.

Your response states that the investigation into the use of RGA test results to determine device hermeticity would be completed by November 30, 2004 and upon completion of this investigation, QP602, "Quality Procedure, Processing, and Analysis of Returned Implantable Cochlear Stimulator Devices", would be updated. The revision of and training on QP602 was scheduled to be completed by December 31, 2004. Additionally, the existing Training of Personnel Operating Procedure, OP 4.9.1, was scheduled to be revised by November 30, 2004. Please provide a copy of the revised procedures, the training documentation, and the RGA investigation data for evaluation. The adequacy and implementation of these changes will be verified during your next scheduled inspection.

- (e) QA continues to attribute the root cause of finding moisture in an explanted device to "loss of hermeticity" even though residual gas analysis showed the presence of helium, an indication that the device may not have manifested a "loss of hermeticity." Thus, the moisture may have resulted from a manufacturing deficiency (see Reference comments in QA Field Return Analysis Report for SN 9727 dated 5/19/04 that moisture was found but no source of leak could be found). Many other devices with RGA testing out of specification for water were found with helium, but the conclusions were that the devices were leakers/loss of hermeticity even though they were still hermetic. This observation indicates that the firm needs a training procedure to identify GMP deficiencies.

Your response states that an investigation into the CLARION® device failures would be completed by November 30, 2004. Please provide documentation of this investigation for review. The results and adequacy of the investigation will be verified during your next scheduled inspection.

4. Failure to establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation, as required by 21 CFR 820.30(b). Specifically, there is no design plan for the proposed retrofit of the ~~PowerPak~~).

Operating procedures OP 2.3.60 Title: Project Plan and OP 2.1.20 Title: Standard Development Process under 5.5 Requirements states "all product development activities shall be accomplished under design controls...Design control includes the process and product development associated with major change(s) to existing product(s)." This policy was not followed in that there were no design controls for the PowerPak modification and there was no written determination that design controls were not necessary.

Your response states that you will create required project documentation for the PowerPak retrofit and that a project plan for this design activity has been generated and is in the approval cycle. You also state that the Program Management function has been restructured and expanded and will provide project status updates on a periodic basis. Additionally, training on the Standard Development Process was scheduled to be completed by November 30, 2004. Please provide documentation of these changes for review. The adequacy and implementation of these changes will be verified during your next scheduled inspection.

5. Failure to document design input requirements which shall be reviewed and approved by a designated individual, as required by 21 CFR 820.30(c). Specifically, the water content limit for the HiRes 90K was not specified in a design input document.

Your response states that you will update the HiRes 90K Functional Specification to include the allowable moisture inside the device to be 5,000 ppm with a pre-bake at 100 degrees C will be completed by December 1, 2004. Please provide the updated Functional Specification for review. The adequacy and implementation of these changes will be verified during your next scheduled inspection.

6. Failure of design verification to confirm that the design output meets the design input requirements, as required by 21 CFR 820.30(f). Specifically, there was no design verification and validation for the HiRes 90K product to meet the water content limit of less than 5,000 ppm (0.500%)

Also, the evaluation of tolerance stacking between the battery and positive battery contact in the battery holder with the insulating washer addition has not been documented for the PowerPak (AA Power Module).

Your response states that the tolerance analysis for the PowerPak has been performed and documented in the engineering report, ER 0868. Additionally, the verification for the moisture content limit will be conducted as part of the vacuum bake revalidation as well as the training on the design verification and validation processes which is scheduled to be completed by Q1 2005. Please provide a copy of the tolerance analysis report for review. The adequacy and implementation will be verified during your next scheduled inspection.

7. Failure to perform risk analysis, as required by 21 CFR 820.30(g). Specifically, the risk analysis is incomplete. Risk analysis was performed using single-point fault conditions, which does not consider "loss of hermeticity" or moisture trapped in a hermetic sealed device which can result in multi-point failure. (Dendrite growth and/or corrosion, shorting and component failures can occur in more than one location in the presence of moisture.)

Your response states that Advance Bionics will revise the Risk Management Operating procedure, OP 2.4.2, to expand the clinical use assessment and generate a guideline document outlining risk considerations for the hazard analysis process by December 31, 2004. The Hazard Analysis for the HiResolution Bionic Ear System will be updated to reflect the new procedure and the training on this is scheduled to be completed by Q1 2005. Please provide a copy of the revised OP 2.4.2 and the hazard analysis guideline document for review. The adequacy and implementation of these changes will be verified during your next scheduled inspection.

8. Failure to adequately ensure that when the results of a process cannot be fully verified by subsequent inspection and testing has not been adequately validated and approved according to established procedures, as required by 21 CFR 820.75(a). Specifically, validation of manufacturing processes has not ensured that devices identified with moisture were hermetically sealed, and that non-hermetically sealed devices (both ceramic & titanium cases) are identified as unacceptable for distribution and implantation.

Two of the three vacuum bake ovens have not been validated.

For the one vacuum bake process (oven C with validation data) to remove moisture, there was no validation plan or protocol, no check list, or other means to ensure procedures were being followed during the operating qualification phase. Also, there was no evidence that a performance qualification phase was conducted. The process validation record showed only three RGA test results (a fourth RGA result was missing in the documents provided for review) for moisture using the RGA test method for residual water analysis. However, it is unknown if these three or four devices were used as part of the process validation. For any single-bake cycle, there are potentially three bake-out ovens available for use. Each oven has 4 chambers capable of holding five devices per chamber. There is also RGA data that may indicate that some devices may not have been sealed with a 25/75 mixture of Helium/Argon specific requirement for subsequent laser welding and Helium fine leak testing.

The helium leak test method validation is not complete. The test method does not ensure that a device passing the fine leak test does not have a gross leak, such as an absent vent hole weld or vent hole incorrectly welded. There is confirmed failure analysis evidence that two devices had gross leaks at the vent hole which resulted in failure and explantation of the devices. There is no means to ensure the Helium is pressurized within the device prior to performing the Helium leak test.

The procedure for laser welding of vent hole allows for up to two laser shots to close the vent hole. The validation protocol does not include the V&V activities for a second shot for closing the vent hole. The procedure specified setting the energy level at 3.0 joules and the process was validated at a 3.1 setting. Qualification of the Helium / Argon gas for the laser welding process was not conducted.

Test method validation of vent hole inspection has not been conducted. Employee training does not include standard training aids, such as examples of acceptable and non-acceptable welded vent holes, color, contaminates, grain structure, etc.

Your response states that Advanced Bionics has revised the Process Validation and Verification Procedure, OP 4.8.1, to comply with established guidelines and principles and will re-validate the helium leak test and laser weld processes by Q1 2005. You state that you will re-validate the vacuum bake process to ensure that the HiRes90K device meets the newly adopted residual moisture specification. Please provide the revised OP 4.8.1 and the validation data for review. The adequacy and implementation of the changes will be verified during your next inspection.

9. Failure to establish and maintain procedures for monitoring and control of process parameters for validated processes, as required by 21 CFR 820.75(b). Specifically, operating procedure OP 4.8.1 "Validation and Verification Procedures" made reference to installation and operation qualification but did not include performance qualification. Furthermore, all procedures contained in this O.P. were not followed. For example, review of documents presented for the validation of the vacuum bake process, excluding the temperature recording chart, had no recording, or any other method, to ensure that the various valve positions are in the proper position to draw a vacuum during the vacuum bake cycle. Failure investigation analysis for S#210218 concluded the device was hermetically sealed in room air.

Your response states that the process validation procedure has been revised and that the vacuum bake process will be validated by Q1 2005. You also state that you will revise Document Action Request/Engineering Order Form (9196175) to record that a revalidation assessment has been performed and to identify if training is required. Please provide a copy of the revised validation

procedure and form 9196175 for review. The adequacy and implementation will be verified during your next scheduled inspection.

10. Failure to review and evaluate the process and perform revalidation when changes or process deviations occur, as required by 21 CFR 820.75(c). Specifically, as early as May 2004 (S#200064, RGA Test Date 5/20/04) failure investigation of explanted devices established that cochlear implants were being returned without evidence of breach hermeticity and failing RGA (residual gas analysis for water/moisture). There was no documented evidence of validation (two ovens have not been validated) or revalidation of the vacuum bake oven process. Process revalidation is necessary to ensure that moisture is being removed from the cochlear implant prior to welding of the vent hole, which hermetically seals the device.

Your response states that the process validation procedure has been revised and that Advanced Bionics will revise Document Action Request/Engineering Order Form (9196175) to record that a revalidation assessment has been performed and to identify if training is required. You also say you will modify OP 2.7.1, Change Control Process to reflect the changes to Form 9196175. These changes were scheduled for release by November 30, 2004. Please provide a copy of the revised process validation procedure, form 9196175, and OP 2.7.1 for review. The adequacy and implementation of these changes will be verified during your next scheduled inspection.

11. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, as required by 21 CFR 820.70(a). Specifically, there is insufficient monitoring and recording of the vacuum pressure to ensure that the vacuum level is maintained throughout the vacuum bake process. Processing chambers are maintaining pressure during transport from vacuum bake oven to laser welding station. The time from removal from vacuum bake cycle to welding of the vent hole and fine leak testing is not recorded.

Please provide for review documentation of the revised procedures and validation you say you have made in response to this observation. The adequacy and implementation of these changes will be verified during your next scheduled inspection.

12. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d). Specifically, acceptance and rejection of production runs, lots, or batches were not complete as products were not sampled and tested to ensure hermeticity sealed products are compliant with moisture specification.

Finished devices are not screened for gross leakage. Visual inspection for gross leak may not be sufficient to detect gross leaks.

Finished device acceptance does not include verification that vacuum was throughout the vacuum bake oven process.

There are no incoming acceptance procedures to ensure that the helium/argon gas mixture meets specification. There are unexplained RGA test results showing the helium argon gas was different than the 25/75 helium argon mix used for back filling the vacuum baked devices.

Your response states that there will be a comprehensive review of process specifications and acceptance criteria that will be required in the Master Validation plan. You also state that the

Receiving Inspection procedure for the gas mixture used has been revised to include a verification and that the HiRes90K assembly procedure would be modified by October 29, 2004. Please provide a copy of the modified HiRes90K assembly procedure and the documentation of the changes to the Master Validation plan for review. The adequacy and implementation of these changes and procedures will be verified during your next scheduled inspection.

13. Failure to investigate the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2). Specifically, investigations of the cause of nonconformities relating to product, processes, and the quality system were not complete. QP602 "Quality Procedure for Processing and Analysis of Returned Implantable Cochlear Stimulator (ICS) Devices" was not complete. The method used to perform the penetrant dye (Zyglo) test uses a 10 psi, which may result in generating false positives for "loss of hermeticity." Determining the loss of hermeticity for a device should be based on both RGA and the Zyglo test results.

DC leakage is not tested for confirmed failed devices that can not be linked.

Your response states that Advanced Bionics will conduct an investigation into the pressure used during the Zyglo test and revise the CAPA procedure, OP 3.6.1, by November 30, 2004. The Quality Procedure, QP602 is scheduled to be revised by October 29, 2004 to include the performance of the DC leakage test on failed devices. Please provide a copy of the revised procedures and the results of the Zyglo test investigation for review. The adequacy and implementation of these procedures and changes will be verified during your next scheduled inspection.

14. Failure to identify the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems, as required by 21 CFR 820.100(a)(3). Specifically, not all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems have been identified. Both defective and non-defective Hi Res 90K explanted devices have been verified with moisture trapped in the hermetically sealed device. Trapped moisture was first identified in May 2004 with explanted devices. This moisture problem potentially could affect hundreds of produced, distributed, stocked and implanted devices. The root cause of the moisture problem has not been identified, the vacuum bake process has not been revalidated, and no new acceptance procedures have been developed. The potential for an inappropriate conclusion of "loss of hermeticity" from zyglo test results showing fluid intrusion has not been investigated.

Your firm's response states that your firm will revise the Corrective and Preventive Action System Operating Procedure, OP 3.6.1, by November 30, 2004, to reflect the changes made to OP 1.1.3, Quality System review. General training for this new CAPA procedure was scheduled to be conducted on December 17, 2004, with further training of the CAPA process to be completed by Q1 2005. Please provide a copy of the revised procedures for OP 1.1.3 (Quality System Review), OP 2.4.2 (Risk Management), OP 3.6.1 (CAPA), OP 4.8.1 (Process Validation and Verification), OP 4.9.1 (Training of Personnel), and OP 6.1.1 (Internal Audit) for review. Also provide documentation of this CAPA training for review. The adequacy and implementation of these procedures and documentation will be verified during your next scheduled inspection.

15. Failure to adequately analyze appropriate sources of quality data to identify existing and potential causes of nonconforming product and other quality problems, as required by 21 CFR 820.100(a)(1). Specifically, review of the failure investigation database showed 237 failures, out of a total of 884 failures, with RGA above the specification limit for residual water. There was no analysis data to

determine how many of the 237 device failures not meeting the limit for water had residual Helium, which would indicate that the device did not lose hermeticity.

Your response states that OP 1.1.3 will be updated to specify the requirement for quarterly Management review meetings and monthly reliability reviews by October 29, 2004. Advanced Bionics will conduct an investigation into failed devices that is scheduled to be completed by November 30, 2004. Please provide a copy of the revised operating procedures and documentation of the failure investigations for review. The adequacy and implementation of these changes will be verified during your next scheduled inspection.

16. Failure to document corrective and preventive action activities including investigations of causes of nonconformities and the actions needed to correct or prevent recurrence of nonconforming product and other quality problems, as required by 21 CFR 820.100(b). Specifically, explanted devices for medical reasons, subsequently found with RGA out of specification for moisture, are not further analyzed to determine the extent of electronic circuit board damage that may have resulted from moisture. DC leakage tests have not been performed for any non-functional explanted devices.

Your response states that a corrective action request for the moisture issue has been generated in your CAPA system. Also, the Quality Procedure, QP602, will be revised by October 29, 2004. Please provide a copy of the corrective action request and the revised QP602 procedure for review. The adequacy and implementation of these changes will be verified during your next scheduled inspection.

17. Failure to ensure 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, as required by 21 CFR 820.100(a)(6). Specifically, the results of additional failure analysis conducted after the original failure investigation has been closed, are not transmitted to QA in a timely manner for consideration. Further, all available information about device failures is not always forwarded to the Agency as updates to the MDR or to comply with PMA conditions of approval.

Your response states that OP 1.1.3 and QP602 will be revised by October 29, 2004. Please provide a copy of these revised procedures for review. The adequacy and implementation of these procedures will be verified during your next scheduled inspection.

18. Failure to establish and maintain procedures for identifying valid statistical techniques as required by 21 CFR 820.250(a). Specifically, there is no information to support the validity of the statistical techniques used in the validation of the vacuum bake process to remove residual moisture before laser welding and hermetically sealing the device.

Your response states that the Process Validation and Verification procedure, OP 4.8.1, will be further revised to include a risk based approach to sample size justification by December 1, 2004 and that Advanced Bionics will initiate a review of all operating procedures that utilize sampling plans to ensure that the requirement for a valid statistical sample size is specified to be released by Q1 2005. Please provide a copy of the revised OP 4.8.1 for review. The adequacy and implementation of these changes will be verified during your next scheduled inspection.

Additionally, the above-stated inspection revealed that your devices are misbranded under section 502(1)(2) of the Act, in that your firm failed or refused to furnish any material or information required

by or under section 519 respecting the device. Specifically, the manufacturer has experienced numerous cochlear implant failures. One of the root causes for some failures was the exposure of the cochlear electronics to moisture in the device housing. A review of failure investigation data for 29 explanted Hi Res 90K devices identified moisture in 12 of 18 (66.6%) devices tested for residual moisture. Your firm has identified moisture in six of eleven (55%) explanted devices (explanted for medical reasons) that were confirmed to be hermetically sealed and still functioning. However, none of this information was reported in your MDRs.

Your response states that Advanced Bionics planned to conduct an investigation for the device failures due to hermeticity to be completed by November 30, 2004. You also state that you will make changes in the quarterly reliability reports. Please provide the investigation data and reliability reports for review. The adequacy and implementation of these changes will be verified during your next scheduled inspection.

On September 23, 2004, a meeting was held with FDA and Advanced Bionics Corporation to discuss the findings from the August 25- September 15, 2004, inspection. During this meeting, you agreed to validate the vacuum bake process, implement a visual inspection of the vent hole, conduct destructive batch testing, correct all observations listed on the FDA 483, and to cease shipment of your devices until your outstanding compliance issues have been resolved.

Until you have adequately demonstrated that you have corrected the violations described above, we continue to believe that the violations still pose a significant risk to the public health.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your quality system.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no applications for premarket approval for devices to which the Quality System regulation deficiencies are reasonably related will be approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be granted until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

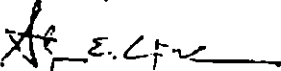
If you have any questions relating to this letter please contact Senior Compliance Officer, Dannie E. Rowland at 949-608-4448.

Please submit your response to:

Jeffrey H. Greiner, President and Co-CEO., Advanced Bionics Corporation
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Sincerely,



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