

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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SETTLEMENT AGREEMENT

THIS SETTLEMENT AGREEMENT is made this 14th day of July, 2008, by and between Complainant Food and Drug Administration ("FDA"), Center for Devices and Radiological Health ("CDRH"), and Respondents Advanced Bionics, LLC ("Bionics") and Jeffrey H. Greiner.

WHEREAS, on July 7, 2008, CDRH filed a Second Amended Administrative Complaint for Civil Money Penalties ("Second Amended Complaint") against Respondents, alleging that Respondents violated 21 U.S.C. § 331(a) by introducing into interstate commerce devices that were adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B);

WHEREAS, on July 9, 2008, Respondents filed their respective Answers to the Second Amended Complaint denying the violations alleged therein;

FDA - 2007-H-0094

SET

WHEREAS, FDA and Respondents, desiring to resolve this proceeding without undertaking costs of further litigation, have agreed to settle this matter, as set forth herein;

WHEREAS, nothing in this Settlement Agreement shall be construed as an admission of liability by Respondents;

WHEREAS Respondents, without admitting the violations alleged in the Second Amended Complaint and disclaiming all liability in connection therewith, and FDA hereby agree to the following:

1. FDA has subject matter jurisdiction, as delegated by the Secretary of Health and Human Services to the Commissioner of Food and Drugs, over this action and personal jurisdiction over Respondents, pursuant to 21 U.S.C. § 333(f). Pursuant to 21 U.S.C. § 333(f)(3)(A), and the implementing regulations at 21 C.F.R. Part 17, the authority to conduct an administrative civil penalty hearing and assess a civil penalty is vested in an administrative law judge appointed in accordance with 5 U.S.C. § 3105.

2. Respondent Bionics shall pay a total of one million one hundred thousand dollars (\$1,100,000). Respondent Greiner shall pay a total of seventy-five thousand dollars (\$75,000). Payment of these sums shall be made within ten (10) days of the entry of this Settlement Agreement by the administrative law judge. Payment must be made by certified checks or money order payable to the United States Treasury.

3. All parties waive any right to a hearing under 21 U.S.C. § 333(f), and any other right that they may have to contest or appeal the payment of the sums agreed to herein.

4. In the event that either Respondent fails to make timely payment of the amount specified in this Settlement Agreement, interest shall automatically accrue on all unpaid amounts at the rate of 15% *per annum*, compounded daily, commencing on the date that payment is due. Complainant may proceed against Respondent for collection of any and all amounts owed by Respondent, including any unpaid balance and interest.

5. If Complainant is required to take administrative or judicial action to enforce this Settlement Agreement, Respondent shall be liable for Complainant's costs of such action, including reasonable attorney fees.

6. Complainant and Respondents shall bear their own costs, including attorney fees, relating to the action underlying this Settlement Agreement.

7. The administrative law judge shall retain jurisdiction of this action until the full amounts due hereunder and any interest, if accrued, are paid. Upon final payment of such amounts, Complainant shall file a Joint Stipulation for Dismissal with Prejudice with the administrative law judge.

8. This Settlement Agreement comprises the entire agreement of the parties with respect to the matters addressed herein. This Settlement Agreement may be modified, amended, or supplemented only by a written instrument signed by the undersigned parties.

9. In exchange for Respondents' payment of the above sums, FDA agrees not to initiate any administrative action (other than those necessary to effectuate Respondents' obligations under this Settlement Agreement) or refer to the Department of Justice any criminal or civil action against Respondents arising from the manufacture or distribution of the HiRes90K cochlear implant device that was known to FDA on or before November

2, 2007. This agreement is binding only on FDA and does not preclude any action by any other agency or government entity. Nor does it preclude FDA from taking any other action based on information unknown to FDA at the time that this Settlement Agreement is executed or from using the evidence described in the Second Amended Complaint in support of future actions based on additional or later conduct.

IT IS SO ORDERED:

Dated this ____ day of _____, 2008.

DANIEL J. DAVIDSON
Administrative Law Judge

For Respondents:

Jeffrey H. Greiner, individually
and on behalf of Advanced Bionics,
LLC, as President and CEO



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Attorney for Jeffrey H. Greiner

For Complainant:

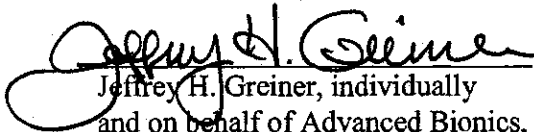
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Center for Devices and
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Gerald F. Masoudi
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Attorney for Complainant CDRH


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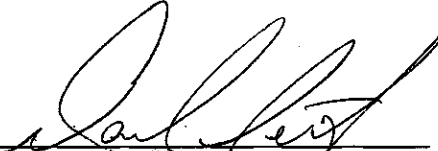
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