

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

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In the matter of )  
)  
Advanced Bionics Corporation, a Corporation, ) ADMINISTRATIVE COMPLAINT  
12740 San Fernando Road ) FOR CIVIL PENALTIES  
Sylmar, California ) FDA Docket: \_\_\_\_\_  
)  
and )  
)  
Alfred E. Mann )  
and )  
Jeffrey H. Greiner, individuals. )  
)  
\_\_\_\_\_)

Complainant, the Center for Devices and Radiological Health (“CDRH”), Food and Drug Administration (“FDA”), United States Department of Health and Human Services, by Wendy S. Vicente, attorney for Complainant, respectfully represents as follows:

**INTRODUCTION**

1. This action is brought by FDA on behalf of CDRH under the Federal Food, Drug, and Cosmetic Act (“the FDCA”), 21 U.S.C. § 333(f),<sup>1</sup> and its implementing regulations, 21 C.F.R. pt. 17, which authorize the imposition of civil penalties against persons who violate the FDCA, 21 U.S.C. §§ 301-397, relating to devices as that term is defined by 21 U.S.C.

<sup>1</sup> This provision was previously designated as 21 U.S.C. § 333(g), but was recently amended to redesignate subsection (g) as subsection (f). Food and Drug Administration Amendments Act of 2007 (FDAAA), Section 226(b)(1), Public Law 110-85 (Sept. 27, 2007).

**2007H-0433**

**LET 1**

1 § 321(h), after an opportunity for a hearing provided in accordance with 5 U.S.C. § 554 and 21  
2 U.S.C. § 333(f)(3)(A).

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4 2. Advanced Bionics Corporation ("Bionics") manufactures a cochlear implant  
5 hearing aid, the HiRes90K Implantable Cochlear Stimulator ("HiRes90K"), which is a device as  
6 defined by 21 U.S.C. § 321(h). The HiRes90K is a class III device and requires approval of a  
7 premarketing approval application ("PMA").

8  
9 3. The HiRes90K is designed to provide useful hearing for individuals with severe  
10 to profound hearing loss via electrical stimulation. The external components include a sound  
11 processor, a head piece, and a cable. The internal components of the device include a receiver  
12 and electrode array that are implanted surgically under the skin behind the ear. The device  
13 converts sound into electrical energy that activates the auditory nerve. The auditory nerve then  
14 sends information to the brain, where it is interpreted as sound. The HiRes90K contains a  
15 "feedthru" assembly to allow for contact between internal electronic components in a  
16 hermetically sealed (*i.e.*, moisture-impervious) case and external components in the device.

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18 4. Bionics received PMA approval for the HiRes90K on July 7, 2003. Since that  
19 time, Bionics has submitted a total of 27 PMA supplements for HiRes90K. With each  
20 supplement approval, FDA included the following statement as part of the device's "Conditions  
21 of Approval": "Before making any change affecting the safety or effectiveness of the device,  
22 submit a PMA supplement for review and approval by FDA . . . ."

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24 5. Shortly after receiving PMA approval in July 2003, Bionics added another  
25 supplier for the feedthru assembly for the HiRes90K device. Although that supplier had been  
26 an approved vendor for a previous version of the cochlear implant system, the new feedthru  
27

1 assembly component was coated with a different material. Bionics did not file a PMA  
2 supplement regarding that change.

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4 6. During an inspection from August 25 to September 15, 2004, FDA determined  
5 that there was an excessive moisture problem in the HiRes90K. The excessive moisture  
6 exposed patients in whom the device was implanted to the risk of device failure and the  
7 associated risks of surgical intervention and potential permanent loss of hearing.

8  
9 7. FDA sent a Warning Letter to Bionics on February 1, 2005, discussing the  
10 problem of excessive moisture, and noting significant deviations from the Good Manufacturing  
11 Practice requirements for medical devices set forth in 21 C.F.R. Part 820. Bionics determined  
12 that the moisture problem related to the feedthru assembly that it had obtained from the  
13 different supplier when it added the supplier in 2003.

14  
15 8. Bionics voluntarily initiated a recall of the HiRes90K devices from that supplier  
16 on March 8, 2006. During a telephone call between personnel at Bionics and FDA on March  
17 15, 2006, the Vice President of Regulatory Affairs for Bionics reported that Bionics had never  
18 notified FDA of the addition of the new supplier for the feedthru assembly in the HiRes90K  
19 device.

20  
21 9. At least two HiRes90K devices containing the feedthru assembly from the  
22 additional supplier were reshipped by Bionics and implanted in patients after the recall was  
23 conducted. Four additional such HiRes90K devices were implanted into patients after the recall  
24 because Bionics failed to adequately notify the facilities to which these devices had been  
25 shipped of the recall. An estimated 3,477 devices with the recalled feedthru assembly are still  
26 implanted. Of those, an estimated 1,502 devices are implanted in children under 18 years old.  
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1 and distribution of devices at 12740 San Fernando Road, Sylmar, California 91342. Mr. Mann  
2 also owns a substantial amount of Bionics' stock.

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4 15. At all times relevant to this action, Respondent, Jeffrey H. Greiner, an individual,  
5 was the president and Co-Chief Executive Officer of Bionics. Mr. Greiner was responsible for  
6 and had the authority over all of the operations at Bionics, including Bionics' manufacturing,  
7 labeling, promoting, holding, selling and distribution of devices at 12740 San Fernando Road,  
8 Sylmar, California 91342.

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10 **STATUTORY AND REGULATORY PROVISIONS**

11 16. The FDCA requires that certain class III devices have an approved premarket  
12 approval application ("PMA"). 21 U.S.C. § 360e(a). If a change is made to a PMA-approved  
13 device that could affect its safety and effectiveness, with limited exceptions not applicable to  
14 this case, the manufacturer must submit a supplement to the premarket approval application  
15 ("PMA supplement") -- and wait for FDA approval -- before implementing that change. 21  
16 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39.

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18 17. In particular, FDA regulations require manufacturers to submit PMA  
19 supplements for changes that affect the safety or effectiveness of the device, and involve (1) the  
20 use of a different facility or establishment to manufacture, process, or package the device (21  
21 C.F.R. § 814.39(a)(3)); or (2) a change in the ingredients of the device (21 C.F.R.  
22 § 814.39(a)(6)).

23  
24 18. A device lacking necessary PMA approval (including approval of supplements)  
25 is deemed adulterated. 21 U.S.C. § 351(f)(1)(B). Each introduction of an adulterated article  
26 into interstate commerce is a prohibited act. 21 U.S.C. § 331(a).  
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<u>Shipping Date</u>	<u>Unit No.</u>	<u>Destination</u>
1/21/2005	25564	Boys Town National Research Hospital, Omaha, Nebraska.
5/19/2005	24202	Medical City Dallas Hospital, Dallas, Texas.
5/24/2005	24208	Penrose St. Francis Hospital, Colorado Springs, Colorado.
5/26/2005	24201	Carle Foundation Hospital, Urbana, Illinois.
6/3/2005	24207	Jewish Hospital Healthcare Network, Louisville, Kentucky.
6/8/2005	24189	Temple University Hospital, Philadelphia, Pennsylvania.
6/29/2005	24197	Phoenix Children's Hospital, Phoenix, Arizona.
7/17/2005	25499	NYU Hospitals Center, New York, New York.
7/21/2005	25549	Boys Town National Research Hospital, Omaha, Nebraska.
7/21/2005	25607	Boys Town National Research Hospital, Omaha, Nebraska.
7/21/2005	25562	Boys Town National Research Hospital, Omaha, Nebraska.
7/21/2005	25601	Boys Town National Research Hospital, Omaha, Nebraska.
7/22/2005	25543	Zale Lipshy University Hospital, Dallas, Texas.
7/22/2005	25603	Medical College of Wisconsin, Wauwatosa, Wisconsin.
7/22/2005	25565	Tampa General Hospital, Tampa, Florida.
7/22/2005	25599	Florida Hospital, Apopka, Florida.
7/22/2005	25570	Zale Lipshy University Hospital, Dallas, Texas.
7/22/2005	25597	Egleston Hospital, Atlanta, Georgia.
7/22/2005	25608	Pitt County Memorial Hospital, Greenville, North Carolina.
7/29/2005	25669	Sinai Grace Hospital, DMC Lasher Ambulatory, Southfield, Michigan.
7/29/2005	25749	Boca Raton Community Hospital, Boca Raton, Florida.
8/5/2005	25514	Tampa General Hospital, Tampa, Florida.
8/18/2005	25505	Baptist Medical Center, Jacksonville, Florida.
8/18/2005	25614	Rocky Mountain Cochlear Implant Center, Englewood, Colorado.

1	8/19/2005	25646	Yale New Haven Hospital, New Haven, Connecticut.
2	8/25/2005	25500	East Alabama Medical Ctr., Opelika Alabama.
3	8/29/2005	25521	Allegheny General Hospital, Pittsburgh, Pennsylvania.
4	8/29/2005	25544	UNC Hospital, Chapel Hills, North Carolina.
5	8/30/2005	25524	Tampa General Hospital, Tampa, Florida.
6	8/30/2005	25533	All Children's Hospital, St. Petersburg, Florida.
7	8/30/2005	25584	Florida Hospital, Apopka, Florida.
8	9/8/2005	25556	NYU Medical Center, New York, New York.
9	9/14/2005	25660	Texas Children's Hospital, Houston, Texas.
10	9/23/2005	25523	Mayo Clinic Hospital, Phoenix, Arizona.
11	9/23/2005	25538	St. Vincent's, Littlerock, Arkansas.
12	9/23/2005	25498	Ochsner Clinic, New Orleans, Louisiana.
13	9/26/2005	25552	Memorial Hermann Southwest Hospital, Houston, Texas.
14	9/27/2005	25520	Children's Medical Center, Dallas, Texas.
15	9/27/2005	25510	Tampa General Hospital, Tampa, Florida.
16	9/27/2005	25508	Children's Healthcare of Atlanta, Atlanta, Georgia.
17	9/27/2005	25548	Medical College of Wisconsin, Milwaukee, Wisconsin.
18	9/27/2005	25553	University of Rochester, Rochester, New York.
19	9/27/2005	25526	Children's Medical Ctr., of Dallas, Dallas, Texas.
20	9/27/2005	25583	University of Cleveland, Cleveland, Ohio.
21	9/28/2005	25611	Virginia Mason Medical Center, Seattle, Washington.
22	9/29/2005	25497	Children's Healthcare of Atlanta, Atlanta, Georgia.
23	9/30/2005	25655	VA Medical Center, 423 23 <sup>rd</sup> Street, New York, New York.
24	10/6/2005	25537	Temple University Children's Hospital, Philadelphia, Pennsylvania.
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1	10/6/2005	25530	Southwest Texas Methodist Hospital, San Antonio, Texas.
2	10/6/2005	25666	Medical City Dallas Hospital, Dallas, Texas.
3	11/18/2005	25507	Riley Hospital, Indianapolis, Indiana.
4	11/18/2005	25653	Riley Hospital, Indianapolis, Indiana.
5	12/5/2005	25503	Children's Memorial Hospital, Chicago, Illinois.
6	12/5/2005	25615	Children's Memorial Hospital, Chicago, Illinois.
7	1/13/2006	28040	University of Utah Hospital & Clinics, Salt Lake City, Utah.
8	1/19/2006	28044	Caroline Medical Center, Charlotte, North Carolina.
9	1/19/2006	28070	Albany Medical Center, Albany, New York.
10	1/20/2006	27984	St. Luke's Hospital of Kansas, Kansas City, Missouri.
11	1/23/2006	28020	Spectrum Health Downtown, Grand Rapids, Michigan.
12	1/23/2006	28014	Sarasota Memorial Hospital, Sarasota, Florida.
13	1/25/2006	28001	Johns Hopkins Listening Center, Baltimore, Maryland.
14	1/25/2006	28060	Johns Hopkins Listening Center, Baltimore, Maryland.
15	1/25/2006	28035	Norton Healthcare, Louisville, Kentucky.
16	1/26/2006	27989	Tampa General Hospital, Tampa, Florida.
17	1/27/2006	28023	Norton Healthcare, Louisville, Kentucky.
18	1/30/2006	27994	Ochsner Foundation Hospital, New Orleans, Louisiana.
19	1/30/2006	28061	St. Johns Regional Health System Springfield, Missouri.
20	2/1/2006	28021	Boys Town National Research Hospital, Omaha, Nebraska.
21	2/2/2006	27986	Deaconess Medical Center, Spokane, Washington.
22	2/2/2006	28033	Medical University of South Carolina, Charleston, South Carolina.
23	2/2/2006	28064	Fletcher Allen Healthcare, Burlington, Vermont.
24	2/13/2006	27985	Kaiser Permanente Hi Moanal, Honolulu, Hawaii.
25	6/16/2006	351042	Urilla, Canada.
26	(received date)		
27	7/7/06	350983	Mindeau, Canada.
28	(received date)		





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301-827-7145 (facsimile)  
wendy.vicente@fda.hhs.gov

DATED: November 2, 2007


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**CERTIFICATE OF SERVICE**

I, Wendy S. Vicente, hereby certify that on the 2nd day of November, 2007, I served via certified mail with a request for a return receipt a copy of the Administrative Complaint for Civil Money Penalties in the above-captioned matter to the following persons:

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

Alfred E. Mann  
Chairman and Co-CEO  
Advanced Bionics Corporation  
12740 San Fernando Road  
Sylmar, CA 91342



Wendy S. Vicente  
Attorney for Complainant  
U.S. Food and Drug Administration  
5600 Fishers Lane (GCF-1)  
Rockville, MD 20857