



9/18/01

WARNING LETTER
VIA EXPRESS MAIL

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

SEP 24 2001

Mr. Jeffrey H. Greiner
President
Advanced Bionics Corporation
12740 San Fernando Road
Sylmar, California 91342

Dear Mr. Greiner:

The Center for Devices and Radiological Health (CDRH) has obtained your firm's literature regarding the "CII Bionic Ear". In your literature it states that the "Food and Drug Administration has approved the CLARION® CII Bionic Ear under rigorous guidelines for proven safety and effectiveness. It is approved to operate in Cochlear Implant mode while the Bionic Ear mode is currently being tested in clinical trials. Upon approval and wide spread release, the Bionic Ear mode will be made available to all existing Bionic Ear recipients through a non-surgical software upgrade." Your literature also states that the CII Bionic Ear has a "faster stimulation rate (1,000,000 updates per second) than conventional cochlear implant technology... through 31 distinct audio processing channels."

The law requires that your firm obtain marketing clearance from the Food and Drug Administration (FDA) before you offer the CII Bionic Ear for sale. CDRH has no record that you obtained marketing clearance for the CII Bionic Ear, and it is therefore in violation of the law. The device is adulterated within the meaning of section 501(f)(1)(B) of the Federal Food, Drug and Cosmetic Act (Act), in that it is a class III device under section 513(f) and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) or an application for an investigational device exemption (IDE) under section 520(g).

The CII Bionic Ear is also misbranded with the meaning of section 502(o), in that a notice or other information respecting the device was not provided to the FDA as required by section 510(k).

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

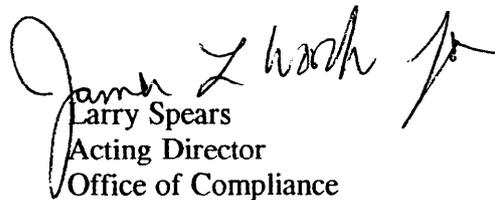
It is necessary for you to take action on this matter now. Please notify this office in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to:

Mr. Ronald L. Swann
Food and Drug Administration
Dental, ENT & Ophthalmic Devices Branch
2094 Gaither Road, HFZ-331
Rockville, MD 20850

Finally, you should understand that there are many FDA requirements pertaining to clinical trials for investigational devices. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers, International and Consumer Assistance (DSMICA, formerly DSMA) at 1(800) 638-2041.

If you have more specific questions about the content of this letter, please feel free to contact Mr. Ernest N. Smith at (301) 594-4613.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Larry Spears", with a stylized flourish at the end.

Larry Spears
Acting Director
Office of Compliance
Center for Devices and Radiological Health