DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 7, 2013

Cochlear Americas
c/o Mr. Sean Bundy
Regulatory and Quality Director
13059 East Peakview Avenue
Centennial, CO 80111

Re: K131240
Trade/Device Name: Cochlear Baha Implant System, Cochlear Baha Attract/Osseointegrated Auditory
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: October 4, 2013
Received: October 7, 2013

Dear Mr. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1. Indications for Use Statement

510(k) Number (if known): K131240

Device Name: Cochlear ™ Baha® Attract

Indications for Use:

The Baha Attract consists of a percutaneously placed Implant Magnet and an external Sound Processor Magnet forming a magnetic connection across healed skin. A Baha Sound Processor is then attached to the Sound Processor Magnet. The Baha Attract is indicated for conductive, mixed and single sided deafness. Patients should have sufficient bone quality and quantity to support successful implant placement.

The Cochlear Baha® Attract is intended for the following patients and indications for use:

- Patients aged 5 and older
- Patients who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3kHz) should be better than or equal to 45 dB HL for use with the BP100 sound processor, and 55 dB HL for use with the BP110 sound processor.
- Bilateral fitting is intended for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conductive thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15dB difference at individual frequencies.
- Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e. Single-sided deafness: SSD™). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL.
- Baha for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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