



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 22, 2015

Cochlear Americas
Ms. Laura Blair AuD
Regulatory Manager
13059 E Peakview Avenue
Centennial, Colorado 80111

Re: K150751

Trade/Device Name: Cochlear™ Baha® Cordelle II Sound Processor
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: March 20, 2015
Received: March 23, 2015

Dear Ms. Blair:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

FDA Form 3514, Section G

510(k) Number (if known): K150751

Device Name: Cordelle II Sound Processor

Indications for Use:

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, Baha 4 and Baha 5 sound processors, 55 dB HL for use with the BP110 sound processor, and better than or equal to 65 dB HL for use with the Cordelle II 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: SSDTM). 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 AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

4. 510(K) Summary

A. Submitter Information

Submitted by: Cochlear Americas
13059 East Peakview Ave.
Centennial, CO 80111

On behalf of the manufacturer: Cochlear Bone Anchored Solutions AB
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B. Date Prepared

3/20/2015

C. Device Class

II

D. Device Name

Trade/Proprietary Name: Cochlear™ Baha® Cordelle II Sound Processor
Common/Usual Name: Auditory Osseointegrated Implant
Classification Name: Hearing Aid (Bone Conduction)
21 CFR 874.3300, Class II
Classification Panel: Ear, Nose, and Throat
Product Code: LXB

E. Predicate Devices

Trade/Proprietary Name: Cochlear™ Baha® Cordelle II Sound Processor
with Baha Softband
Common/Usual Name: Auditory Osseointegrated Implant Sound Processor
with Softband
Classification Name: Hearing Aid (Bone Conduction)
21 CFR 874.3300, Class II
Classification Panel: Ear, Nose, and Throat
Product Code: LXB
510(k): K080363

Trade/Proprietary Name: Cochlear™ Baha® Attract
Common/Usual Name: Auditory Osseointegrated Implant Sound Processor
Classification Name: Hearing Aid (Bone Conduction)

Classification Panel
Product Code:
510(k):

21 CFR 874.3300, Class II
Ear, Nose, and Throat
LXB
K131240

F. Purpose of Submission

The purpose of this Traditional 510(k) is to expand the fitting indications of the Baha Attract System to include the use of the Cordelle II Sound Processor and the fitting range that is currently indicated for the Cordelle II Sound Processor with the titanium abutment and Baha softband. The current indications for the Cordelle II Sound Processor were cleared 4/10/2008 under 510(k) K080363.

G. Device Description

The technology base for the Baha implant was originally derived from the 1952 discovery by Dr. Per-Ingvar Brånemark that titanium was biocompatible with bone, leading to the term “osseointegration”. The Brånemark System, as it would later be known, formed the basis for the rapid development and widespread implementation of root form endosseous dental implants, now safely and effectively used by many hundreds of thousands of people worldwide. Root form dental implants share many characteristics with the Baha implant component including material, conformation, and surgical implantation procedures.

The Cochlear Baha Attract auditory implant system consists of three parts: a titanium implant, a titanium-encased magnet pair, and an external magnet pair with a replaceable soft pad. The existing range of Baha sound processors attach to this external magnet via a snap coupling. The system works by utilizing natural bone transmission as a pathway for sound to travel to the inner ear, bypassing the external auditory canal and middle ear. After surgical placement, the titanium implant naturally integrates with the skull bone over time through a process known as osseointegration. The external sound processor transmits sound vibrations through the transcutaneous magnetic coupling to the titanium implant. The vibrating implant creates vibrations within the skull that stimulate the nerve fibers of the inner ear, allowing hearing.

The change proposed in this Traditional 510(k) is to expand the fitting indications of the Baha Attract to include the use of the Cordelle II Sound Processor and the fitting range that is currently indicated for the Cordelle II Sound Processor with a titanium abutment or softband. The fundamental operating principle of the device (hearing rehabilitation through bone conduction) remains unchanged.

H. Intended Use

The Baha implant system is intended for treatment of patients who have conductive or mixed hearing loss as a result of certain medical conditions such as bilateral atresia and chronic supportive otitis media, and for those who have Single-Sided Deafness (SSD) caused by a congenital condition, surgery, trauma, or disease. The intended use of the system is to provide an implanted magnet, and a transcutaneous magnetic connection of an external sound processor, in this instance, the Cordelle II Sound Processor. 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, Baha 4 and Baha 5 sound processors, 55 dB HL for use with the BP110 sound processor, and better than or equal to 65 dB HL for use with the Cordelle II 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 (Le. Single-sided deafness: SSDTM). 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.

I. Technological Characteristics

The Cochlear Baha Attract consists of five basic components, none of which are new to this submission:

- An implanted magnet
- An implanted fixture to act as an anchoring point for the implanted magnet (The BI300, cleared in K100360)
- An external magnet for attachment to the Sound Processor (referred to as the SP Magnet) in a variety of magnetic strengths
- A patient-replaceable SP Magnet soft pad to equalize peak skin pressures across the interface between the SP Magnet and the patient's skull
- An existing, cleared Baha sound processor (currently consisting of either the BP100, Baha 4, Baha 5 or BP110, cleared in K090720, K132278, K142907 and K110996 respectively)

The Baha Cordelle II Sound Processor is an external sound processor that utilizes analog signal processing with K-Amp circuitry (Killion, 1993) for use with the Baha auditory osseointegrated implant. The Cordelle II Sound Processor is often chosen for a patient who has greater gain needs since it offers the highest output levels and K-Amp circuitry that helps prevent saturation.

J. Materials

The Baha Cordelle II Sound Processor has not changed in design, materials, or manufacturing since the 510(k) clearance of the 65dB indication with the titanium implant and softband (K080363). This 510(k) premarket notification is solely for an indication change, and therefore, this section does not apply to this submission.

K. Performance Data

Technical feedback and force transfer measurements with the Cordelle II Sound Processor used with the Baha Attract System were completed in support of this 510k submission. The focus of the test report was on comparing the Baha Attract System with Cordelle II Sound Processor against the Baha Softband with Cordelle II Sound Processor. The results of the bench testing support the conclusion that the performance of the Cordelle II Sound Processor with Baha Attract is substantially equivalent to the Cordelle II Sound Processor used with the Baha Softband.

L. Conclusion

Based on the indications for use, technological characteristics, and substantial equivalence comparison to the predicate devices, the Cordelle II Sound Processor has been shown to be safe and effective for its proposed intended use with the Baha Attract System.