



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

Cochlear Americas
Mr. Tristan Manus
Regulatory Affairs Specialist
13059 E. Peakview Ave.
Centennial, CO 80111

Re: K153245
Trade/Device Name: Baha 5 Super Power Sound Processor
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: January 29, 2016
Received: February 1, 2016

Dear Mr. Manus:

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,


Kesia Alexander

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

4. Indications for Use Statement

510(k) Number (if known): K153245

Device Name: Cochlear™ Baha® 5 SuperPower Sound Processor

Indications for Use:

The Cochlear™ Baha® 5 SuperPower Sound Processor 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 65 dB HL for use with the Baha 5 SuperPower 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-conduction thresholds are defined as less than a 10 dB average difference between ears (measure at 0.5, 1, 2, and 3 kHz), or less than a 15 dB 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 (measure 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 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)

K153245

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
Konstruktionsvagen 14
SE-435 33 Molnlycke
Sweden
(Establishment Number 9616024)

Contact:

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B. Date Prepared

November 6th 2015

C. Device Class

II

D. Device Name

Trade/Proprietary Name:

Cochlear™ Baha® 5 SuperPower Sound
Processor

Common/Usual Name:

Hearing Aid (Bone Conduction)

Classification Name:

Hearing Aid, Bone Conduction, Implanted
21 CFR 874.3300, Class II

Classification Panel:

Ear, Nose, and Throat

Product Code:

LXB

510(k):

K153245

E. Predicate Device

(Primary)

Trade/Proprietary Name:

Cordelle II Sound Processor

Common/Usual Name:

Auditory Osseointegrated Implant

Classification Name:

Hearing Aid, Bone Conduction, Implanted
21 CFR 874.3300, Class II

Classification Panel

Ear, Nose, and Throat

Product Code:

LXB

510(k):

K150751

(Secondary)

Trade/Proprietary Name:

Baha 5 Sound Processor

Common/Usual Name:

Auditory Osseointegrated Implant

Classification Name:

Hearing Aid, Bone Conduction, Implanted
21 CFR 874.3300, Class II

Classification Panel:

Ear, Nose, and Throat

Product Code:
510(k):

LXB
K142907

F. Purpose of Submission

This submission is adding the Cochlear™ Baha® 5 SuperPower Sound Processor to the series of processors offered by Cochlear Bone Anchored Solutions (BAS). The Cochlear™ Baha® 5 SuperPower Sound Processor functions by combining the external sound processor with an abutment and a small titanium implant placed that is placed in the skull behind the ear through a simple surgical procedure. The sound processor transmits acoustic signals into electrical signals when then causes mechanical action in the transducer to transmit sound transcranially to the functioning auditory system.

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. Unlike hearing aids, the Baha hearing system utilizes a natural bone conduction pathway to send sound directly to a cochlea with residual functionality. The Baha system combines an external sound processor, in this application the Cochlear™ Baha® 5 SuperPower Sound Processor, with an abutment and small titanium implant placed into the bone through a simple surgical procedure. The implant subsequently forms an osseointegrated bond with the surrounding bone, allowing transmission of high-quality sound directly to the inner ear, bypassing a damaged outer or middle ear. The Baha system provides an alternate pathway for patients who may not benefit from wearing an air-conduction hearing aid. The changes introduced in this 510(k) are specific to the sound processor, not the abutment/implant or magnet. These changes culminate as the next generation Baha sound processor that provides recipients with moderately severe hearing loss (up to 65dB SNHL) access to sound. The Cochlear™ Baha® 5 SuperPower Sound Processor includes a decoupling of the microphone/processor and the actuator unit to allow various wearing options. The wearing options allow the recipient to achieve maximum gain while minimizing the likelihood of feedback. The design has been modified to incorporate a new rechargeable lithium-ion battery pack which provides the power needed for recipients with up to 65dB SNHL measured by pure tone average bone-conduction hearing thresholds at 0.5, 1, 2, and 3 kHz. This change does not modify the intended functionality or fundamental operating principles of the implant/abutment system.

H. Intended Use

The Cochlear™ Baha® 5 SuperPower Sound Processor 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 suppurative otitis media, and for those who have Single-Sided Deafness (SSD) caused by a congenital condition, surgery, trauma, or disease.

I. Indications for Use

The Cochlear™ Baha® 5 SuperPower Sound Processor has the following indications for use:

- Patients of any age for use with the Baha Softband or headband. Patients aged 5 and older for use with the Baha auditory osseointegrated implant system.

- 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 3 kHz) should be better than or equal to 65 dB HL.
- Bilateral fitting is intended for patients who meet the criterion in both ears, with bilateral symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conduction 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 15 dB 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.

J. Technological Characteristics

The Cochlear™ Baha® 5 SuperPower Sound Processor has the same intended use, the same mechanical design, the same functional characteristics, the same fundamental operating principles, and is made of biocompatible materials as the predicate devices.

K. Materials

The Cochlear™ Baha® 5 SuperPower Sound Processor is made of medical grade plastics and metals that have been shown to be biocompatible and safe for human use.

L. Performance Data

Performance testing was conducted to compare the Cochlear™ Baha® 5 SuperPower Sound Processor with the predicate implant / abutment systems. Substantial equivalence to the predicate device was accomplished through environmental testing, reliability and durability testing, electrical interface testing, and functional and performance testing. The results demonstrated the Cochlear™ Baha® 5 SuperPower Sound Processor is functionally equivalent to the predicate devices.

M. Conclusion

Based on the indications for use, technological characteristics, and substantial equivalence comparison to the predicate device, the Cochlear™ Baha® 5 SuperPower Sound Processor has been shown to be safe and effective for its intended use.