DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 20, 2016

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

Re: K161123
Trade/Device Name: Baha 5 Power Sound Processor
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: April 20, 2016
Received: April 21, 2016

Dear Dr. 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161123

Device Name
Cochlear TM Baha® 5 Power Sound Processor

Indications for Use *(Describe)*
The Cochlear Baha® 5 Power Sound Processor is intended for the following patients and indications for use:

*Patient 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 3kHz) should be better than or equal to 55 dB HL.

*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 (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 deadness: 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K161123

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 Konstruktionsvägen 14 SE-435 33 Mölnlycke Sweden (Establishment Number 9616024)
Contact:	Laura Blair Regulatory Manager Cochlear Americas lblair@cochlear.com (303) 524-6852 (o) (303) 524-6825 (f)

B. Date Prepared	April 20th 2016
C. Device Class	II
D. Device Name	Cochlear™ Baha® 5 Power Sound Processor

Trade/Proprietary Name:	Cochlear™ Baha® Implant System
Common/Usual Name:	Bone Anchored Sound Processor
Classification Name:	Hearing Aid, Bone Conduction, Implanted 21 CFR 874.3300, Class II
Classification Panel	Ear, Nose, and Throat
Product Code:	LXB
510(k):	K161123

E. Predicate Devices

(Primary)

Trade/Proprietary Name:	Baha BP110 Sound Processor
Common/Usual Name:	Auditory Osseointegrated Implant Sound Processor
Classification Name:	Hearing Aid, Bone Conduction, Implanted 21 CFR 874.3300, Class II
Classification Panel	Ear, Nose, and Throat
Product Code:	LXB
510(k):	K110996

(Secondary)

Trade/Proprietary Name:	Baha 5 Sound Processor
Common/Usual Name:	Auditory Osseointegrated Implant Sound Processor
Classification Name:	Hearing Aid, Bone Conduction, Implanted 21 CFR 874.3300, Class II
Classification Panel	Ear, Nose, and Throat
Product Code:	LXB
510(k):	K142907

F. Purpose of Submission

This submission requests the addition of the Baha 5 Power Sound Processor to the series of sound processors offered by Cochlear Bone Anchored Solutions (CBAS). The Baha 5 Power Sound Processor functions by combining the external sound processor with an abutment (the Connect system) or with a magnet (the Attract system) and small titanium implant that is placed in the skull behind the ear during a simple surgical procedure. The sound processor transmits acoustic signals into electrical signals which then causes mechanical action in the transducer to transmit sound transcranially to the functioning auditory system.

The subject of this **Special 510(k): Device Modification** is a modification to the Cochlear™ Baha® BP110 sound processor, which was cleared under 510(k) K110996 on May 10th, 2011 for unilateral or bilateral use with conductive and mixed hearing losses, or for single-sided deafness (SSD). The modified device will have the same indication as the primary predicate device. The secondary predicate is the Baha 5 Sound Processor, cleared under 510(k) K142907 on 3/25/2015. The Baha 5 Sound Processor is also cleared for unilateral or bilateral use with conductive and mixed hearing losses, or for single-sided deafness (SSD). The secondary predicate device shares many features with the proposed modified device, and is included to allow comparison of those features. The subject of this submission, the modified sound processor, will be called the Baha 5 Power Sound Processor.

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 Baha Power Sound processor, with small titanium implant placed into the bone through a simple surgical procedure. The implant is either attached to the sound processor via an abutment or internal titanium-encased magnet paired with an external magnet. 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 only to the sound processor. There are no changes to the abutment/implant or magnet.

The modified sound processor, the Baha 5 Power Sound Processor is an upgrade to the currently marketed BP110 Sound Processor (which it will replace on the US market) and the Baha 5 Sound Processor. The Baha 5 Power Sound Processor provides gain sufficient to match the Indications for Use of the currently marketed BP110 Sound Processor. As the modified device utilizes the same fundamental scientific principles, the same intended use and indications for use as the current legally marketed primary predicate device it will replace, and merely represents improvements in features that are the same as those used in another Cochlear Baha sound processor that has already been cleared for marketing for a less hearing-impaired population (the model Baha 5 Sound Processor, cleared under K142907), we believe these modifications are appropriate for the Special 510(k) process.

The Baha 5 Power Sound Processor does not modify the intended functionality or fundamental operating principles of the implant/abutment system.

H. Intended Use

The new Baha 5 Power Sound Processor will be used as an external sound processor option (in the Cochlear Baha family of sound processors) to conduct sound energy directly to the cochlea via a Baha auditory osseointegrated implant, or via transcutaneous transmission with a Baha headband or Softband.

This is the same intended use as the current legally marketed, unmodified BP110 Sound Processor (the primary predicate device that it will replace) and the Baha 5 Sound Processor (the secondary predicate).

I. Indications for Use

The Cochlear Baha® 5 Power Sound Processor is intended for the following patients and indications for use:

- Patient 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 3kHz) should be better than or equal to 55 dB HL.
- 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 (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 deadness: 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 Baha 5 Power 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 like the predicate devices.

The modified sound processor will still be compatible with the currently marketed Softband/headband (cleared under K002913 and letters to file under this clearance), and the currently marketed auditory osseointegrated implants (BIA300 system, cleared under K100360 and BA400 cleared under K121317 as well as the Baha Attract cleared under K131240), and will also be backward compatible with the original auditory osseointegrated implant (cleared under K955713).

K. Materials

The Baha 5 Power 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

Bench testing was conducted to compare the Cochlear Baha® 5 Power Sound Processor with the predicate implant / abutment systems. Substantial equivalence to the predicate devices was accomplished through environmental testing, reliability and durability testing, electrical interface testing, and functional testing. The results demonstrated the Cochlear Baha 5 Power 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 devices, the Baha 5 Power Sound Processor has been shown to be safe and effective for its intended use.