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

Cochlear Americas
Beth Murray
Senior Regulatory Affairs Specialist
13059 E. Peakview Avenue
Centennial, CO 80111

June 7, 2017

Re: K171088
Trade/Device Name: Cochlear™ Baha® SoundArc
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: May 12, 2017
Received: May 15, 2017

Dear Beth Murray:

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 B. 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)*
K171088

Device Name
Cochlear Baha® SoundArc

Indications for Use *(Describe)*

The Cochlear Baha® SoundArc is intended for test situations and for patients who cannot or choose not to have an implant for the following indications for use:

• Patients of any age 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 Power and Baha 5 Power sound processors, and better than or equal to 65 dB HL for use with the Cordelle II and Baha 5 SuperPower Sound Processors.

• 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.

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.

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K171088

Cochlear™ Hear now. And always.

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:	Beth Murray Senior Regulatory Affairs Specialist Cochlear Americas bemurray@cochlear.com (303) 264-2318 (o) (303) 524-6825 (f)

B. Date Prepared	April 11, 2017
C. Device Class	II
D. Device Name	Cochlear™ Baha® SoundArc
Trade/Proprietary Name:	Baha SoundArc
Common/Usual Name:	Headband for Bone Conduction Hearing Aid
Classification Name:	Hearing Aid, Bone Conduction, Implanted 21 CFR 874.3300, Class II
Classification Panel	Ear, Nose, and Throat
Product Code:	LXB

E. Predicate Device(s)

Trade or Proprietary Name:	Cochlear™ Baha® system
Common/Usual Name:	Implanted Bone Conduction Hearing Aid
Classification Name:	Bone Conduction Hearing Aid
Classification Status:	Class II, 21 CFR §874.3300
Product Codes:	LXB
Panel:	Ear Nose and Throat Devices Panel
Primary System Predicate	Baha headband/Softband, K002913
Secondary System Predicates:	Sound Processors of the Baha system: K080363, K090720, K110996, K132278, K142907, K153245, K161123

F. Purpose of Submission

The purpose of this Special 510(k) is to introduce a new style of headband, known as Baha SoundArc, which can be used by people of any age and attaches to the existing cleared Baha sound processors. Baha SoundArc provides a more discrete alternative to the currently marketed non-surgical bone conduction options offered by Cochlear Bone Anchored Solutions (CBAS).

G. Device Description

Baha SoundArc is an encapsulated spring wire that wraps around the back of the head and sits behind and above the ears. SoundArc is designed with a symmetrical disc holder that holds the Baha sound processor in place, and is compatible with existing Baha sound processors. The design of SoundArc enables the Baha device to be placed against the skull for operation without the need for a Baha implant to be placed.

H. Intended Use

The Baha 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 Baha SoundArc, the subject of this Special 510(K), provides a discreet point for connection of existing external Baha sound processors for long-term use on persons of any age, without the need for surgery. The Baha SoundArc may also be used in test situations. The Baha SoundArc does not modify the intended use, functionality, or fundamental operating principles of the Baha system.

I. Indications for Use

The Cochlear Baha® SoundArc is intended for test situations and for patients who cannot or choose not to have an implant for the following indications for use:

- Patients of any age 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 Power and Baha 5 Power sound processors, and better than or equal to 65 dB HL for use with the Cordelle II and Baha 5 SuperPower Sound Processors.
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- 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.

J. Technological Characteristics

Like the existing Baha Softband and headband, SoundArc transfers vibrations from the sound processor to the mastoid through the skin, without the need for surgery. SoundArc has the same intended use as the currently cleared Baha system, and the same fundamental operating principles and functional characteristics as the existing non-surgical bone conduction headband and Softband for Baha. The existing cleared range of Baha sound processors attach to the SoundArc in the same manner as the predicate device, through snap coupling.

K. Materials

The following new materials in direct and prolonged contact have been evaluated per 10993-1 and shown to be biocompatible and safe for human use:

- Silopren LSR 4040
- Grilamid L 25 (polyamide) Natural 6112

L. Performance Data

Performance testing was conducted based on a comparison between the proposed SoundArc and the legally marketed Softband and the current Baha sound processors of the predicate Baha system. Substantial equivalence to the predicate system was accomplished through functional and performance tests, design and specification analysis, and biocompatibility evaluation. The results demonstrated the Baha SoundArc is functionally equivalent to the predicate system.

M. Conclusion

Based on the indications for use, technological characteristics, and substantial equivalence comparison to the predicate system, SoundArc has been shown to be safe and effective for its intended use.