December 19, 2018

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

Re: K182116
Trade/Device Name: BA310 Abutment, BIA310 Implant/Abutment
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: MAH
Dated: November 19, 2018
Received: November 20, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182116

Device Name

Cochlear Baha Connect System

Indications for Use *(Describe)*

The Cochlear Baha Connect System (Baha sound processors and implant/abutment system) 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 Baha 4 and Baha 5 sound processors, 55 db HL for use with the Baha 5 Power sound processors, and 65 db HL for use with the 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: 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.

Specific models of the Cochlear Baha abutments can be used with either the Cochlear Baha Connect System or compatible sound processors from Oticon Medical AB. Refer to the Cochlear Baha abutment labeling for a list of compatible Oticon Medical sound processors.

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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1. 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 Email: bemurray@cochlear.com (303) 264-2318 (o) (303) 524-6825 (f)

Date Prepared **August 02, 2018**

B. Device Name and Classification Information

Trade Name:	Cochlear ™ Baha® Implant System
Common or Usual Name:	Bone Conduction Hearing Implant System
Classification Name:	Hearing Aid, Bone Conduction, Implanted 21 CFR 874.3300, Class II
Classification Panel:	Ear, Nose, and Throat
Product Codes:	MAH

C. Predicate Devices:

Device	510(k) no.	Manufacturer
BA300 Cochlear Baha Abutment (primary predicate device)	K100360	Cochlear Bone Anchored Solutions AB
BA400 Cochlear Baha Abutment (additional predicate device)	K121317	Cochlear Bone Anchored Solutions AB
Ponto System (additional predicate device)	K161671	Oticon Medical AB

Device Description

Intended Use

The Cochlear Baha Connect 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 osseointegrated fixation point for connection of an external sound processor. The intended use remains unchanged from the predicate device.

Indications for Use

The Cochlear Baha Connect System (Baha sound processors and implant/abutment system) 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 Baha 4 and Baha 5 sound processors, 55 db HL for use with the Baha 5 Power sound processors, and 65 db HL for use with the 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: 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.

  Specific models of the Cochlear Baha abutments can be used with either the Cochlear Baha Connect System or compatible sound processors from Oticon Medical AB. Refer to the Cochlear Baha abutment labeling for a list of compatible Oticon Medical sound processors.

Technological Characteristics

The BA310 abutments are modifications of the previously cleared BA300 abutments and provide additional sound processor compatibility than the previously cleared abutments. A bone anchored hearing system consists of a sound processor connected to an implant with a skin penetrating abutment. The implant is surgically anchored in the skull bone behind the ear. Vibrations generated by the sound processor are transmitted via the implant directly through the skull bone to the cochlea as bone conduction sound. Compared to the currently cleared BA300 and BA400 Abutments, a small "flange" has been added to the upper part of the BA310 Abutment and the core diameter of the abutment has been reduced by 0.7mm. This design allows sound processors from Oticon Medical to snap on the outside of the abutment while maintaining the same snap in coupling design for connection to Baha sound processors. It was identified that the design change may have an impact on the surgical procedure if changing from a BA300 or BA400 abutment to a BA310 abutment. It was also identified that due to the close contact between the soft tissue and the snap on coupling connection of the Oticon Sound Processor, there may be an impact on soft tissue reaction. Both of these potential issues are mitigated through recommendations added to the BA310 surgery guide and any residual risk is regarded as acceptable when weighed against the benefit of the Baha system.

Performance Data

Pertinent dimensions of the BA310 Abutment were designed to permit compatibility between the Oticon Medical Ponto sound processors and BA310/BIA310 abutments/implants, and also between Cochlear Baha sound processors. The Cochlear Baha sound processor and Baha BA310 Abutment snap in coupling connection has been tested in cross combination with the Oticon Medical Ponto sound processor with snap on coupling connection. Rotation torque, snap force, bend force and frequency testing verifies the compatibility of both Oticon Medical Ponto sound processors and Cochlear Baha sound processors with the BA310 Abutment.

Substantial Equivalence

The Baha system with modified abutment has the same intended use, same indications, same principles of operations, and same materials as compared to the predicate Baha abutment. The only technological difference is a simple design change to the abutment. The updated labelling accounts for the abutment diameter change when changing from the BA300 or BA400 abutment to the BA310 abutment and accounts for the closer contact of Oticon Medical's sound processors snap coupling to the soft tissue. All design requirements were met and the conclusions drawn from non-clinical testing and analysis demonstrate the modified abutment is as safe, as effective, and performs as well as the previously cleared versions of the Baha system and Ponto abutment.

The minor design change has been accounted for through labeling recommendations and verified as safe and effective through non-clinical testing. It can be concluded that the BA310/BIA310 Abutments are substantially equivalent.