DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 25, 2015

Cochlear Americas
Mr. Sean Bundy
Director, Regulatory Strategy
13059 East Peakview Avenue
Centennial, CO 80111

Re: K142907
Trade/Device Name: Baha 5 Sound Processor
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid, Bone Conduction
Regulatory Class: Class II
Product Code: LXB
Dated: February 20, 2015
Received: February 23, 2015

Dear Mr. Bundy,

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,

Deborah L. Falls -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

# Indications For Use

**510(k) Number** (if known): K142907
**Device Name**: Cochlear™ Baha® 5 Sound Processor
Indications for Use Statement:
The Cochlear Baha 5 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 45 dB HL.
- Bilateral fitting is intended for patients who meet the 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 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.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C) (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

# 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided.

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

Manufactured by:
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Date Submission Prepared:
December 2014

Device Name:

| | |
|---|---|
| *Trade or Proprietary Name*: | Cochlear™ Baha® 5 Sound Processor |
| *Common or Usual Name*: | Osseointegrated Auditory Prosthesis Sound Processor |
| *Classification Status:* | Class II, 21 CFR §874.3300 |
| Product Codes: | LXB |
| *Panel:* | Ear Nose and Throat Devices Panel |

Device Description:

The subject of this 510(k) is a modification to the Cochlear Baha 4 sound processor, which was cleared under 510(k) K132278 for unilateral or bilateral use with conductive and mixed hearing losses (as a result of congenital malformations such as atresia, or certain medical conditions such as chronic suppurative otitis media), and for cases of single-sided sensorineural deafness (SSD, caused by a congenital condition, surgery, trauma or disease). The Baha system has been marketed for more than 30 years throughout the world, and there are now more than 100,000 users of a Baha system globally.

Baha sound processors can be used with either the external Baha headband or Softband in persons of any age, or for children aged 5 or older with the Baha auditory osseointegrated implants. The external Baha headband or Softband system works via conventional transcutaneous bone conduction amplification. The Baha implant system works by combining the external sound processor with an abutment and a small titanium implant placed in the skull behind the ear in a simple surgical procedure. The system is based on the process of "osseointegration" through which living tissue integrates with titanium in the implant. Thus, the titanium implant becomes one with the surrounding bone, allowing high-quality amplified and processed sound from the Baha sound processor to be conducted via an abutment or a magnetic coupling to the skull bone and directly to a cochlea with residual functionality. For either form of transmission, the processed sound either bypasses a conductive block in those patients with conductive or mixed hearing loss, or transfers sound through the skull to the opposite-ear normal cochlea for patients with SSD.

The modified sound processor, the Baha 5 is an upgrade to the currently marketed Baha 4 sound processor. The Baha 5 sound processor has the same signal processing functionality as the Baha 4, but incorporates a new transducer into a smaller outer casing while providing comparable output. The modified device utilizes the same fundamental scientific principles, and has the same intended use and indications for use as the current legally marketed device it will replace. In addition, the Baha 5 is compatible with the same range of 2.4GHz devices currently marketed for use with the Baha 4, but also incorporates Bluetooth functionality directly into the device without the need for an external accessory. The Baha 5 also supports a mobile medical app, the Baha Smart App, which acts as an enhanced remote control for the device, and offers improved auditory streaming capabilities and mobile phone integration.

Intended Use:

The new Baha 5 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 implant, or via transcutaneous transmission with a Baha headband or Softband. This is the same intended use, and for the same patient population, as the current legally marketed, unmodified Baha 4 device (the predicate device that it will replace). The Baha Smart App is intended to supplement the existing range of accessories for the sound processor, and acts as a more fully-featured remote control than those currently available.

Technological Characteristics:
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 implant (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).

The primary modifications proposed are to the size and shape of the device, as well as the incorporation of a smaller vibrating transducer. The modified transducer provides comparable output to the currently marketed device, while allowing for a smaller overall design. In addition, the 2.4 GHz technology has been updated to incorporate Bluetooth in addition to the current wireless communications protocol. Compatibility with the existing range of wireless accessories is maintained.

The Baha Fitting Software (also cleared under K132278) has been updated to support the fitting of the modified device, but is largely unchanged in terms of capability.

Summary of Testing:
Testing of the Baha 5 included testing to confirm patient safety, product usability and reliability, interoperability, and electromagnetic compatibility. Patient safety testing included biocompatibility testing as well as basic medical electrical safety testing. Usability was demonstrated through simulated use testing in a variety of use cases. Reliability testing was conducted through exposure of the device to mechanical stresses, and environmental extremes, and simulated long-term use followed by functional testing. Interoperability testing was performed including functional testing with existing Baha fixation systems, as well as the ability to perform a prescribed fitting through the Baha Fitting Software. Curves for the maximum output force level at OFL90 and full on gain at OFL 60 were generated, and verified in comparison to target outputs and to previous Baha processors. Verification of the implementation of the firmware was also performed, including functional testing of the firmware-enabled features of the device. Testing of the Bluetooth capability of the device included functional testing of pairing, audio streaming and remote control functionality of the Baha Smart App. Compatibility with the existing range of wireless accessories was established, and testing of the range of the wireless link was performed. Electromagnetic compatibility testing established that the device did not emit excessive amounts of electromagnetic energy, and that the device operated as intended in the presence of interference sources. Coexistence testing was performed, with the device paired and in a streaming configuration while exposed to various sources of in-band interference. The results of the testing indicate that the Baha 5 is substantially equivalent to the predicate device.

Conclusions:
Despite the changes to the physical components of the device, the Baha 5 sound processor has substantially equivalent function and technology, and the same intended use as the predicate Baha 4 sound processor cleared for marketing under K132278. The indication for use statement is also the same as that for the current legally marketed Baha 4 sound processor that it will replace.