February 23, 2021

Cochlear Americas
Krystal Haley
Regulatory Affairs Specialist II
10350 Park Meadows Drive
Lone Tree, Colorado 80124

Re: K202048
Trade/Device Name: Cochlear Baha 6 Max Sound Processor, Cochlear Baha Fitting Software 6, Cochlear Baha Smart App
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: January 22, 2021
Received: January 25, 2021

Dear Krystal Haley:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shu-Chen Peng, Ph.D.
Acting Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
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Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K202048

Device Name
Cochlear Baha 6 Max Sound Processor, Cochlear Baha Fitting Software 6, Cochlear Baha Smart App

Indications for Use *(Describe)*
The Cochlear Baha 6 Max Sound Processor is intended for the following patients and indications for use:

• Patient of any age for use with the Baha Softband (or headband) or Baha SoundArc. 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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**510(k) Summary** K202048

## A. Submitter Information

Submitted by:

Cochlear Americas
10350 Park Meadows Drive
Lone Tree, CO 80124

On behalf of the manufacturer:

Cochlear Bone Anchored Solutions AB
Konstruktionsvägen 14
SE-435 33 Mölnlycke
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(Establishment Number 9616024)

Contact:

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## B. Date Prepared

**23-July-2020**

## C. Device Name and Classification

Device Names

Cochlear Baha 6 Max Sound Processor
Cochlear Baha Fitting Software 6
Cochlear Baha Smart App

Trade/Proprietary Name:

Cochlear Baha 6 Max Sound Processor
Cochlear Baha Fitting Software 6
Cochlear Baha Smart App

Common/Usual Name:

Baha 6 Max Sound Processor
Baha Fitting Software 6
Baha Smart App

Classification Name:

Hearing Aid, Bone Conduction
21 CFR 874.3300, Class II

Classification Panel

Ear, Nose, and Throat

Product Code:

LXB

## D. Predicate Device

Trade/Proprietary Name:

Cochlear Baha 5 Power Sound Processor
Cochlear Baha Fitting Software 5
Cochlear Baha 5 Smart App

| | |
|---|---|
| Common/Usual Name: | Baha 5 Power Sound Processor<br>Baha Fitting Software 5<br>Baha 5 Smart App |
| Classification Name: | Hearing Aid, Bone Conduction<br>21 CFR 874.3300, Class II |
| Classification Panel | Ear, Nose, and Throat |
| Product Code: | LXB |
| 510(k): | K161123 |

**E. Purpose of Submission**

This Traditional 510(k) seeks clearance for the addition of the Baha 6 Max Sound Processor to the series of sound processors offered by Cochlear Bone Anchored Solutions (CBAS). The Baha 6 Max Sound Processor converts acoustic signals (sound) into electrical signals, which then generates mechanical action (vibration) from the actuator. The vibrations transmit sound transcranially to the auditory system. In addition to the Baha 6 Max Sound Processor, this 510(k) seeks clearance for the Baha Fitting Software 6, software that is necessary to program the Baha 6 Max Sound Processor, and the Baha Smart App, a smart phone application that allows recipients to monitor and control their sound processor.

**F. Device Description**

The Cochlear Baha bone conduction hearing system provides an alternate solution for patients who may not benefit from an air-conduction hearing aids. Unlike air-conduction hearing aids, the Baha system utilizes a natural bone conduction pathway to send sound directly to the inner ear (cochlea), bypassing a damaged outer or middle ear. The Baha bone conduction hearing system has non-surgical and surgical options. For the non-surgical option, the external sound processor, which converts acoustic sound into mechanical vibrations, is securely placed behind the ear with a Baha Softband or Baha SoundArc. For the surgical option, the external sound processor is coupled with an abutment (Baha Connect) or magnet (Baha Attract). The mechanical vibrations travel through the abutment or magnet to a small, titanium implant, which is surgically placed into the bone. The titanium implant has an osseointegrated bond with the surrounding bone, allowing transmission of high-quality sound directly to the inner ear.

The Baha 6 Max Sound Processor is a modification of the previously cleared Baha 5 Power Sound Processor (K161123). The changes introduced in this 510(k) are specific to the sound processor and accessories, and do not affect the cleared Softband, SoundArc, Baha Connect abutments, Baha Attract magnet, or the BI300 titanium implant. The Baha 6 Max Sound Processor does not modify the intended functionality or fundamental operating principles of the bone conduction hearing system. The changes within culminate as the next generation Baha sound processor that provides recipients with moderate hearing loss, up to 55 dB, access to sound.

The Baha 6 Max Sound Processor will be supported by a new fitting software, Baha Fitting Software 6, and a new app, Baha Smart App.

**G. Intended Use**

The Cochlear Baha System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing. The Baha 6 Max Sound Processor is intended to be used as part of the Cochlear Baha System to pick up surrounding sound and transfer it to the skull bone via a Baha Implant, Baha Softband or Baha SoundArc and can be used unilaterally or bilaterally.

**H. Indications for Use**

The Cochlear Baha 6 Max Sound Processor is intended for the following patients and indications for use:

- Patient of any age for use with the Baha Softband (or headband) or Baha SoundArc. 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.

**I. Technological Characteristics and Comparison to Predicate**

The Baha 6 Max Sound Processor has the same intended use, a similar mechanical design, the same functional characteristics, the same fundamental operating principles, and is made of biocompatible materials like the predicate device.

The modified sound processor is compatible with the currently marketed Softband/headband (cleared under K002913 and letters to file under this clearance), the currently marketed SoundArc (cleared under K171088) and the currently marketed auditory osseointegrated implant (BIA300 system, cleared under K100360, BA400, cleared under K121317, and the Baha Attract cleared under K131240), and will also be backward compatible with the original auditory osseointegrated implant (cleared under K955713).

Like the predicate, the Baha 6 Max Sound Processor has an LED visual indicator and an available tamper resistant battery door. The primary modifications are the introduction of the BC Drive II actuator and the Xidium platform, and optimizations to the hardware.

- The BC Drive II actuator was optimized to be smaller than the actuator in the predicate.
- The Xidium platform has improved processing power and lower power consumption than the predicate, contributing to minor changes to the sound processing features.
- The hardware was optimized and is now less prone to feedback. Additionally, the sound processor is available with either of the following installed: a shorter snap coupling, resulting in a lower profile than the predicate, or an extended snap coupling, with the same profile as the predicate.
- The new sound processor features include improved feedback suppression, impulse noise reduction, and improved directionality for bilateral recipients. The sound processor also has direct audio streaming for iPhone and selected Android phones and the ability to upgrade the firmware remotely.

The above changes resulted in a smaller, lighter sound processor that uses a smaller battery while achieving the same fitting range (55 dB) as the predicate.

**Table 1** summarizes a comparison of the features, functions, and performance data for the Baha 6 Max Sound Processor and the Baha 5 Power Sound Processor (predicate device).

**Table 1. Baha 5 Power Sound Processor and the Baha 6 Max Sound Processor Comparison Summary**

| Characteristic | Baha 5 Power Sound Processor Predicate K161123 | Baha 6 Max Sound Processor |
|---|---|---|
| System compatibility | All percutaneous and transcutaneous Baha systems, including the original Baha implant (K955713), the BIA300 implant (K100360), the Baha Softband or headband (K002913), the Baha SoundArc (K171088) and the Baha Attract (K131240).<br><br>Compatible with accessories that use GN Hearing wireless communications protocol. Also Made For iPhone. | Baha 6 Max Sound Processor has the same system compatibility with an addition of compatibility with select Android phones. |
| Exterior design | LED, program button, volume rocker, and battery door (which can be replaced with tamper resistant door) | The Baha 6 Max has a new LED, program button, tamper resistant door, and rounder shape. It does not have a volume rocker. |
| Battery size and type | 675 (zinc-air) | 312 (zinc-air) |
| Materials | Made of medical grade plastics and metals that have been shown to be biocompatible and safe for human use | Equivalent – There are two new materials in the Baha 6 Max. All materials are biocompatible. |

| Characteristic | Baha 5 Power Sound Processor Predicate K161123 | Baha 6 Max Sound Processor |
|---|---|---|
| Snap Coupling for attachment | The predicate snap coupling is used to the connect the sound processor to implant systems. | The snap coupling has the same function, but it is also available in a shorter configuration. |
| Actuator | Electromagnetic<br>BCDrive I | Electromagnetic<br>BCDrive II |
| Platform | Ardium | Xidium |
| Basic Signal and Processing Features | 17 channel sound analysis | Same |
| | 4 user-defined programs and dedicated listing programs for | Same |
| | Wide-band Dynamic Range Compression | Same |
| | Active Balanced Directionality | Same with added bilateral compression |
| | Noise Management II | Same |
| | Dual Track Feedback Manager | Same |
| | Dedicated fitting rationales for mixed loss, conductive loss, and SSD | Same |
| | 2.4 GHz wireless technology | Same |
| | Scene Classifier | Same |
| | Post Auricular Position Compensation | Same |
| | Wireless Fitting | Same |
| | The predicate did not have Impulse Noise Control | Baha 6 Max Sound Processor offers Impulse Noise Control, which reduces the volume of sudden loud sounds. |
| Remote Firmware Upgrade | The predicate did not have Remote Firmware Upgrades | Remote Firmware Upgrade is available through the Baha Smart App |
| Software | Baha Fitting Software 5 | Baha Fitting Software 6 |
| | Baha 5 Smart App | Baha Smart App |

This 510(k) submission also includes Baha Fitting Software 6 and Baha Smart App. The predicate device for Baha Fitting Software 6 is Baha Fitting Software 5, which is used to program the previous generation of Baha sound processors. The reference device for the Baha Smart App is the Osia Smart App due to the number of shared features that are not available on the Baha 5 Smart App, which is used with the previous generation of Baha sound processors. The features and functions for the Baha Fitting Software 6 and the Baha Smart App are compared to their respective predicate and reference devices in **Table 2** and **Table 3** respectively.

**Table 2. Baha Fitting Software 5 and the Baha 6 Fitting Software Comparison Summary**

| Characteristic | Baha Fitting Software 5 Predicate (K161123) | Baha 6 Fitting Software |
|---|---|---|
| Compatibility | Programs a Baha 5 Sound Processor | Equivalent – programs a Baha 6 Max Sound Processor |
| Programming interface | Wired and Wireless | Equivalent – BFS 6 is wireless only. |
| Fitting Features | Enter and/or acquire patient indications | Same |
| | Enter and/or acquire BC Audiograms | Same |
| | Perform in-situ tone audiometry | Same |
| | Perform in-situ feedback measurement | Same |
| | Prescribe based on individual indications and thresholds | Same |
| | Adjust gain and MPO settings based on individual preferences | Equivalent – the gain model was slightly updated for Baha 6 Max Sound Processor. |
| | Configure signal processing features based on recommendations and individual preference | Equivalent – BFS 6 offers an additional Impulse Noise Reduction feature |
| | Set up to four programs: Every day, Noise, Outdoor, and Music | Same |
| | Wireless accessories can be paired and mixed | Equivalent – Wireless accessories can be paired, mixed, and fine tuned |
| | Bilateral SP pairing | Same |
| | LED and Beep alert control | Equivalent – there is an additional LED option for Baha 6 Max Sound Processor |

**Table 3. Osia Smart App and the Baha Smart App Comparison Summary**

| Characteristic | Osia Smart App Reference (K191921) | Baha Smart App |
|---|---|---|
| Compatibility | Supports the Osia 2 Sound Processor | Supports the Baha 6 Max Sound Processor |
| | Available on iOS and Android | Yes |
| Sound Processor Support Features | Adjust the volume and gain equalizer (treble, mid, and bass) on SP | Same |
| | Pre-set sound suggestions without noise reduction features | Pre-set sound suggestions with Noise Reduction and Impulse Noise Reduction |
| | Activate and Control Cochlear Wireless Accessories | Same |

| Characteristic | Osia Smart App Reference (K191921) | Baha Smart App |
|---|---|---|
| | Change programs on the sound processor and activate wireless streaming | Same |
| | Link a personalized program to specific locations | Same |
| Information available with App | View the battery and connection status | Same |
| | View SP information: model, serial number, firmware version, and hardware version | Same |
| | View SP usage and data logging | Same |
| | Locate SP | Same |
| Remote Firmware Upgrade | Does not have Remote Firmware Upgrades | Remote Firmware Upgrade is available through the Baha Smart App for the Baha 6 Max Sound Processor |

## J. Performance Data

Bench testing was conducted to compare the Baha 6 Max Sound Processor with the Baha 5 Power Sound Processor, including use with the predicate implant / abutment systems. Substantial equivalence to the predicate device was accomplished through functionality and performance testing, hardware and interface testing, reliability and environmental testing, as well as system and subsystem level testing. Software verification and validation of Baha Fitting Software 6 and Baha Smart App was also completed to establish that the software are functionally equivalent to their respective predicate and reference devices and support substantial equivalence. The results demonstrated the Baha 6 Max Sound Processor is functionally equivalent to the Baha 5 Power Sound Processor.

## K. Conclusion

Based on the indications for use, technological characteristics, and performance data, the Baha 6 Max Sound Processor, Baha Fitting Software 6, and Baha Smart App have been shown to be substantially equivalent in comparison to the predicate device.