May 29, 2025

Cochlear
Denis Dimartino
Senior Regulatory Affairs Specialist
10350 Park Meadows Drive
Lone Tree, Colorado 80214

Re: K250215
Trade/Device Name: Baha 7 Sound Processor; Baha Fitting Software 7 (P2121898); Baha Smart App (iOS) (P1646054); Baha Smart App (Android) (P1646035); Baha SoundBand
Regulation Number: 21 CFR 874.3302
Regulation Name: Bone-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: May 5, 2025
Received: May 5, 2025

Dear Denis Dimartino:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
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Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250215

Device Name

Baha 7 Sound Processor;
Baha Fitting Software 7 (P2121898);
Baha Smart App (iOS) (P1646054);
Baha Smart App (Android) (P1646035);
Baha SoundBand

Indications for Use *(Describe)*

The Cochlear Baha 7 Sound Processor is intended for the following patients and indications for use:
• Patient of any age for use with the Baha SoundBand, 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.

510(k) Summary

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 Sweden (Establishment Number 9616024)
Contact:	Denis DiMartino Senior Regulatory Affairs Specialist Cochlear Americas ddimartino@cochlear.com 508-304-4356

B. Date Prepared **24-January-2025**

C. Device Name and Classification

Device Names	Cochlear™ Baha® 7 Sound Processor Cochlear™ Baha® Fitting Software 7 Cochlear™ Baha® Smart App Cochlear™ Baha® SoundBand
Trade/Proprietary Name:	Cochlear™ Baha® 7 Sound Processor Cochlear™ Baha® Fitting Software 7 Cochlear™ Baha® Smart App Cochlear™ Baha® SoundBand
Common/Usual Name:	Baha 7 Sound Processor Baha Fitting Software 7 Baha Smart App Baha SoundBand
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® 6 Max Sound Processor Cochlear™ Baha® Fitting Software 6

	Cochlear™ Baha® Smart App Cochlear™ Baha® Softband
Common/Usual Name:	Baha 6 Max Sound Processor Baha Fitting Software 6 Baha Smart App Baha Softband
Classification Name:	Hearing Aid, Bone Conduction 21 CFR 874.3300, Class II
Classification Panel	Ear, Nose, and Throat
Product Code:	LXB
510(k):	K202048

E. Purpose of Submission

This Traditional 510(k) seeks clearance for the addition of the Baha 7 Sound Processor to the series of sound processors offered by Cochlear. The Baha 7 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 7 Sound Processor, this 510(k) seeks clearance for the Baha Fitting Software 7 (software that is necessary to program the Baha 7 Sound Processor) the Baha Smart App (a smart phone application that allows recipients to monitor and control their sound processor), and the Baha SoundBand (a non-surgical retention option for the Baha sound processors).

F. Device Description

The Cochlear Baha bone conduction hearing system provides an alternate solution for patients who may not benefit from air-conduction hearing aids. Unlike air-conduction hearing aids, the Baha implant 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 SoundBand, 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 7 Sound Processor is a firmware variant of the previously cleared Baha 6 Max Sound Processor (K202048). The changes introduced in this 510(k) are specific to the sound processor and accessories, and do not affect the cleared Baha Connect abutments, Baha Attract magnet, the BI300 titanium implant, Baha Softband, or Baha SoundArc. The Baha 7 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

supports Bluetooth LE Audio streaming, which enables compatibility with the new generation wireless accessories from GN Hearing.

The Baha 7 Sound Processor will be supported by a new fitting software (Baha Fitting Software 7), an updated app (Baha Smart App), and a new non-surgical retention option (Baha SoundBand).

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 7 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 SoundBand, Baha Softband or Baha SoundArc™ and can be used unilaterally or bilaterally.

H. Indications for Use

The Cochlear™ Baha® 7 Sound Processor is intended for the following patients and indications for use:

- Patient of any age for use with the Baha SoundBand, 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.

Technological Characteristics and Comparison to Predicate

The Baha 7 Sound Processor has the same intended use, the same external hardware, similar 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).

The primary modifications to the Baha 7 Sound Processor relate to improved connectivity, achieved by the new Dooku3 platform (new firmware). An overview of the new features of the Baha 7 Sound Processor is provided below:

- Bluetooth LE Audio, including Auracast
  - Ensure the device supports the future of audio streaming, including broadcasting using Auracast.
  - Offers more possibilities to access streamed signals, both in terms of personal audio sharing and location based or local audio sharing.
- Compatibility with the New Wireless Accessories from GN (implementing LE Audio)
  - Ensure support for full functionality with the new Wireless Accessories from GN, the TVStreamer+ and Multi-Mic+
- An additional color option to appeal to the pediatric segment.
- New laser etching on the device.

Table 1 summarizes a comparison of the features, functions, and performance data for the Baha 7 Sound Processor and the Baha 6 Max Sound Processor (Predicate device system).

Table 1: Baha 6 Max Sound Processor and the Baha 7 Sound Processor Comparison Summary

Characteristic	Baha 6 Max Sound Processor	Baha 7 Sound Processor
System compatibility	All percutaneous and transcutaneous Baha systems, including the original Baha implant with the BA210 (K955713), the BIA300 implant [BI300 implant with the BA300 abutment] (K100360), BA310 abutment, and the Baha Attract (K131240). All non-surgical Baha systems, including the Baha Softband or headband (K002913) and Baha Soundarc (K171088).	Baha 7 Sound Processor has the same system compatibility, with an addition of compatibility with the Baha SoundBand.
	Made for iPhone Hearing Device ASHA protocol for compatible Android Phones	Similar – Baha 7 has increased compatibility with Bluetooth LE Audio
	Compatible with accessories that use the GN Hearing Wireless communications protocol	Similar – Baha 7 introduced support for full functionality with the new Wireless

Characteristic	Baha 6 Max Sound Processor	Baha 7 Sound Processor
		Accessories, the TVStreamer+ and Multi-Mic
Battery size and type	312 (zinc-air)	Same
Materials	Made of medical grade plastics and metals that have been shown to be biocompatible and safe for human use	Equivalent, with the exception of one new color option available for Baha 7 SP (lavender).
Snap Coupling for attachment	The predicate snap coupling is used to the connect the sound processor to implant systems.	Equivalent
Actuator	Electromagnetic BCDrive II	Electromagnetic BCDrive II
Firmware Platform	Dooku2 (Xidium)	Dooku3 (Rhodium)
Basic Signal and Processing Features	4 user-defined programs, which may use dedicated listing programs for every day, outdoor, noise, and music	Similar, the programs now use streaming
	Active Balanced Directionality	Same
	Noise Management II	Same
	Dedicated fitting rationales for mixed loss, conductive loss, and SSD	Same
	2.4 GHz wireless technology	The Baha 7 SP supports additional technology: LE Audio for streaming of audio from smart phones and the wireless accessories to Baha 7 Sound processors BLE based protocol Auracast for streaming of audio from Auracast transmitters
	Scene Classifier	Same
	Wireless Fitting	Same
	Baha 6 Max Sound Processor offers Impulse Noise Control, which reduces the volume of sudden loud sounds.	Same
Remote Firmware Upgrade	Remote Firmware Upgrade is available through the Baha Smart App	Same
Software	Baha Fitting Software 6	Baha Fitting Software 7
	Baha Smart App v1.1	Baha Smart App v1.2

This 510(k) submission also includes the Baha Fitting Software 7, Baha Smart App, and Baha SoundBand. The predicate device for Baha Fitting Software 7 is Baha Fitting Software 6, which is used to program the previous generation of Baha sound processors. The predicate device for

the Baha Smart App is the previous version of the Baha Smart App, which is used with the previous generation of Baha sound processors. The predicate device for the Baha SoundBand is the Baha Softband, which is a similar non-surgical retention item for the sound processors. The Baha Fitting Software 7, the Baha Smart App, and Baha SoundBand are compared to their respective predicate devices in **Table 2**, **Table 3**, and **Table 4**, respectively.

Table 2: Baha Fitting Software 6 and Baha Fitting Software 7 Comparison Summary

Characteristic	Baha Fitting Software 6	Baha Fitting Software 7
Compatibility	Programs a Baha 6 Max Sound Processor	Programs a Baha 7 Sound Processor
Programming Interface	Wireless	Same
Functions	Datalogging and FW upgrade functionality	BFS 7 has improved datalogging and FW upgrade functionality. It is intended to improve user experience and has no effect on the safety or clinical performance. BFS 7 also introduces new VerfitLINK and DSL-BCD functions, which are both optional features.
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	Same
	Configure signal processing features based on recommendations and individual preference	Same
	Set up to four programs: Every day, Noise, Outdoor, and Music	Same
	Wireless accessories can be paired and mixed, and fine tuned	BFS7 allows for support of additional new wireless accessories
	Bilateral SP pairing	Same
	LED and Beep alert control	Same

Table 3: Baha Smart App Comparison Summary

Characteristic	Baha Smart App v1.1	Baha Smart App v1.2
Compatibility	Supports the Baha 5 and Baha 6 Max Sound Processor	Supports the Baha 5, Baha 6 Max and Baha 7 Sound Processors
	Available on iOS and Android	Same
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	Same
	Activate and Control Cochlear Wireless Accessories	The BSA v1.2 version includes support for new Wireless Accessories that are compatible with Baha 7 Sound Processor
	Change programs on the sound processor and activate wireless streaming	Same
	Link a personalized program to specific locations	Same
Information available within 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 Lost SP	Same
Remote Firmware Upgrade	Update the firmware on the Sound Processor via the Smart App	Same

Table 4: Baha Softband and Baha SoundBand Comparison Summary

Characteristic	Baha Softband	Baha SoundBand
Patient Population	The Baha Softband is intended for Baha Sound Processor recipients of any age, no health conditions specified.	Equivalent. The Baha SoundBand is intended for Baha Sound Processor recipients of any age, no health conditions specified.

Characteristic	Baha Softband	Baha SoundBand
Operating Principle	The Baha Softband combines an elastic band with a connector disc to which the sound processor is attached. It is available in both unilateral (one connector disc) and bilateral (two connector discs) versions. The Baha Softband is placed around the head with the connector disc(s) positioned behind the ear in the mastoid region.	Similar. The Baha SoundBand combines an elastic band with a connector disc to which the sound processor is attached. The Baha SoundBand is placed around the head with the connector disc(s) positioned behind the ear in the mastoid region.
Design	Adjustable soft band available in multiple colors, bilateral and unilateral fitting.	Similar. Flexible textile band with adjustable length. It is available with one or two connector discs (unilateral or bilateral version) which are adjustable on the band.
Patient Contacting Materials	Biocompatibility evaluation completed per 10993-1. The materials have been evaluated and concluded biocompatible.	Equivalent, biocompatibility evaluation completed per 10993-1: 2018. The materials have been evaluated and concluded biocompatible.
Method of Attachment to Sound Processor	Snap coupling technology	Equivalent
Compatible Sound Processors	Supports the Baha 5 and Baha 6 Max Sound Processor	Supports the Baha 5, Baha 6 Max Sound Processor, and Baha 7 Sound Processor

I. Performance Data

Testing of the Baha 7 Sound Processor and components included biocompatibility, software, electromagnetic compatibility, and bench testing.

- Biocompatibility evaluation and testing demonstrated that the materials, packaging residuals, and the input from the manufacturing process are biocompatible.
- Software testing was performed for the Baha Fitting Software 7 and Baha Smart App. The testing demonstrated that the software supported the clinician fitting and recipient control of the Baha 7 Sound Processor.
- Electromagnetic compatibility testing established that the sound processor did not emit excessive amounts of electromagnetic energy, and that it operated as intended in the presence of interference sources.
- Bench functionality and performance testing included functional and performance testing, hardware and interface testing, reliability and environmental testing, as well as system

and subsystem level testing. The bench testing demonstrates that the Baha 7 SP does not result in additional safety or efficacy concerns in comparison to the predicate.

The results demonstrated the Baha 7 Sound Processor is functionally equivalent to the Baha 6 Max Sound Processor.

J. Conclusion

Based on the indications for use, technological characteristics, substantial equivalence comparison to the predicate device, and performance data, the Baha 7 Sound Processor and components has been shown to be as safe and effective as the predicate device for its intended use.