September 29, 2021

Cochlear Americas
Whitney Alexander
Regulatory Affairs Specialist II
10350 Park Meadows Dr
Lone Tree, Colorado 80124

Re: K212136
Trade/Device Name: Cochlear Baha 6 System, Cochlear Baha Fitting Software 6, Cochlear Baha Baha Smart App
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: July 7, 2021
Received: July 8, 2021

Dear Whitney Alexander:

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.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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)*

K212136

Device Name

Cochlear™ Baha® 6 System

Indications for Use *(Describe)*

The Cochlear™ Baha System 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.

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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:	Whitney Alexander Regulatory Affairs Specialist II Cochlear Americas walexander@cochlear.com (303) 264-2153 (o) (303) 524-6825 (f)

B. Date Prepared **7-July-2021**

C. Device Name and Classification

Device Names:	Cochlear™ Baha® 6 System Cochlear™ Baha® Fitting Software 6 Cochlear™ Baha® Baha Smart App
Trade/Proprietary Name:	Cochlear™ Baha® System Cochlear™ Baha® Fitting Software 6 Cochlear™ Baha® Baha Smart App
Common/Usual Name:	Cochlear™ Baha® System 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

Device Names:	Cochlear™ Baha® 6 System Cochlear™ Baha® Fitting Software 6 Cochlear™ Baha® Baha Smart App

Trade/Proprietary Name:	Cochlear™ Baha® System Cochlear™ Baha® Fitting Software 6 Cochlear™ Baha® Baha Smart App
Common/Usual Name:	Baha 6 System 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
510(k):	K202048

E. Purpose of Submission

This Traditional 510(k) seeks clearance for the implementation of Remote Assist via updates made to Baha Fitting Software 6 and Baha Smart App offered by Cochlear Bone Anchored Solutions (CBAS). Together with the Baha 6 Sound Processor, these components make up the Baha 6 System. The Baha Fitting Software 6 is necessary to program the Baha 6 Max Sound Processor, which 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. The Baha Smart App is a smartphone application that allows recipients to monitor and control their sound processor. Implementation of Remote Assist expands Cochlear's Connected Care offerings to enable real-time, more convenient, and less burdensome clinical care for clinicians and recipients.

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 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 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 updates made to Baha Fitting Software 6 and Baha Smart App add Remote Assist capabilities to the previously cleared Baha Fitting Software 6 and Baha Smart App (K202048). The changes introduced in this 510(k) are specific to the fitting software and smart app, and do

not affect the cleared Baha 6 Max Sound Processor, Softband, SoundArc, Baha Connect abutments, Baha Attract magnet, or the BI300 titanium implant. Introduction of Remote Assist does not modify the intended functionality or fundamental operating principles of the bone conduction hearing system.

By introducing Remote Assist, the healthcare professional can:

- Communicate in real-time via video, audio, or messaging, and
- Connect to and remotely adjust the recipient's Baha 6 Max Sound Processor through the Baha Fitting Software 6 and Baha Smart App interface.

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 Fitting Software is used to program a Cochlear Baha Sound Processor and modify hearing profiles in order to provide comfortable and usable gain for Baha System recipients. The Baha Smart App is a software application intended to remotely control and monitor a Baha Sound Processor directly from a smartphone.

H. Indications for Use

The Cochlear™ Baha System 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 updated Baha 6 System, which includes changes to the Baha Fitting Software 6 and Baha Smart App, has the same intended use, the same algorithms for programming the sound processor, the same overall functional characteristics, and the same fundamental operating principles as the predicate Baha 6 System.

Table 1 summarizes a comparison of the technological characteristics of the currently available Baha 6 System (predicate device) with updated Baha 6 System (subject device). Because the

changes to the system are for the software components, comparison has been included for the fitting software and smart app.

Table 1: Comparison summary of Baha 6 System

Technological Characteristic	Baha 6 System (Subject)	Baha 6 System (Predicate)
Compatible Sound Processor	Baha 6 Max Sound Processor	Same
Connected Care Features	• Remote Firmware Updates of SP • Remote programming through smartphone interface to connect BFS and Baha 6 Max SP via the Baha Smart App • Live video, audio, and chat between BFS and Smart App	• Remote Firmware Updates of SP • Remote programming via clinician control of computer with BFS shipped to recipient
Baha Fitting Software 6 Features		
Patient Information	Enter and/or acquire patient information	Same
Prescription Features	• Enter and/or acquire BC Audiograms • Perform in-situ tone audiometry • Perform in-situ feedback measurement • Informs clinician if high background noise is present during BC direct or feedback measurement. • Allows creation of prescription file without connecting sound processor to BFS 6	• Enter and/or acquire BC Audiograms • Perform in-situ tone audiometry • Perform in-situ feedback measurement
Fitting Features	• Prescribe based on individual indications and thresholds • Adjust gain and MPO settings based on individual preferences • Configure signal processing features based on recommendations and individual preference • Set up to four programs: Every day, Noise, Outdoor, and Music	Same
Saving the session	Store the fitting session to the sound processor, the PC hard drive, or to a network location	Same

Technological Characteristic	Baha 6 System (Subject)	Baha 6 System (Predicate)
Software Level of Concern	Minor	Same
Baha Smart App Features		
Control Sound Processor Features	• Adjust the volume on sound processor • Adjust gain equalizer (treble, mid, and bass) on sound processor • Choose from pre-set sound suggestions, which can enable Noise Reduction and Impulse Noise Reduction • Change programs on the sound processor • Link a personalized program to specific locations	Same
Wireless Accessories features	• Control Cochlear Wireless Accessories • Activate wireless streaming	Same

Information available within the app	• View the battery and connection status
	• View sound processor usage and data logging
	• sound processor information:
	  ○ model
	  ○ serial number
	  ○ firmware version
	  ○ hardware version
		Same

Device Registration	Capability to register sound processor to user's Cochlear account	Not completed within app
Software Level of Concern	Minor	Same

The above changes to the Baha 6 System results in software with added functionalities, primarily additional remote programming capabilities, compared to the predicate system. By implementation of these additional capabilities, Cochlear can expand its Connected Care Services portfolio to provide both clinicians and recipients a more streamlined and improved user experience.

J. Performance Data

Bench testing was conducted to compare the updated Baha 6 System with the cleared Baha 6 System. Substantial equivalence to the predicate system was demonstrated through verification

and validation testing. Verification activities included software testing of new features and regression testing of existing functionality at both the component and system level. Smoke testing, functional test cases (e.g., measurements and programs), non-functional test cases (e.g., cybersecurity and deployment) and hazard control verification were completed. At the system level, integration, performance, and design analysis tests were run.

Validation activities included design validation and summative usability testing. The completed design validation demonstrates compliance of the new features with user needs and intended use. In the usability testing, participants were asked to complete a series of tasks throughout a Remote Assist session, and feedback was collected afterwards.

The testing results demonstrate the updated Baha 6 System, including the updated Baha Fitting Software 6 and Baha Smart App, are functionally equivalent to the cleared Baha 6 System.

K. Conclusion

Based on the indications for use, technological characteristics, substantial equivalence comparison to the predicate device, and performance data, implementation of Remote Assist via updates made to Baha Fitting Software 6 and Baha Smart App, which are the software components of the Baha 6 System, have been shown to be as safe and as effective for their intended uses compared to the predicate Baha 6 System.