July 10, 2026

Cochlear Americas
Denis Dimartino
Senior Regulatory Affairs Specialist
10350 Park Meadows Dr.
Lone Tree, Colorado 80124

Re: K260902
Trade/Device Name: Cochlear™ Osia® System: Cochlear™ Osia® 3(I) Sound Processor;Cochlear™ Osia® 3 Sound Processor; Cochlear™ Osia® 3 Charger; Cochlear™ Osia® 3 Aqua+; Cochlear™ Osia® Fitting Software 3; Cochlear™ Osia® Smart App
Regulation Number: 21 CFR 874.3340
Regulation Name: Active Implantable Bone Conduction Hearing System
Regulatory Class: Class II
Product Code: PFO
Dated: June 8, 2026
Received: June 8, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

JOYCE C.
LIN -S

for 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260902

Please provide the device trade name(s).

Cochlear™ Osia® System:
Cochlear™ Osia® 3(I) Sound Processor;
Cochlear™ Osia® 3 Sound Processor;
Cochlear™ Osia® 3 Charger;
Cochlear™ Osia® 3 Aqua+;
Cochlear™ Osia® Fitting Software 3;
Cochlear™ Osia® Smart App;

Please provide your Indications for Use below.

The Osia System is intended for the following patients and indications:
• Patients 5 years of age or older.
• Patients who have a conductive or mixed hearing loss (up to 65 dB HL sensorineural hearing loss) and still can benefit from sound amplification. Patients with mixed hearing loss should be evaluated according to the fitting range of the sound processor in combination with the implant used.
• Bilateral fitting of the Osia System is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies.
• Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., single-sided deafness or "SSD"). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz).
• The Osia System 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.
• Prior to receiving the device, it is recommended that an individual have experience with appropriately fitted air conduction or bone conduction hearing aids.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

A. Submitter Information

Submitted by:	Cochlear Americas 10350 Park Meadows Drive Lone Tree, CO 80124
On behalf of the manufacturer:	Cochlear Ltd – Macquarie 1 University Avenue Macquarie University, NSW 2109 Australia (Establishment Number 3009092818)
Contact:	Whitney Alexander Senior Regulatory Affairs Specialist Cochlear Americas walexander@cochlear.com 719-337-8620

B. Date Prepared **8-July-2026**

C. Device Name and Classification

Device Names:	Cochlear Osia 3(I) Sound Processor Cochlear Osia 3 Sound Processor Cochlear Osia 3 Charger Cochlear Osia 3 Aqua+ Cochlear Osia Fitting Software 3 Cochlear Osia Smart App
Trade/Proprietary Name:	Cochlear™ Osia® System
Common/Usual Name:	Osia System
Classification Name:	Active implantable bone conduction hearing system 21 CFR 874.3340, Class II
Classification Panel:	Ear, Nose, and Throat
Product Code:	PFO

D. Predicate Device

Device Names:	Cochlear™ Osia® 2(I) Sound Processor Cochlear™ Osia® 2 Sound Processor Cochlear™ Osia® 2 Aqua+ Cochlear™ Osia® Fitting Software 2 Cochlear™ Osia® Smart App

Trade/Proprietary Name:	Cochlear™ Osia® System
Common/Usual Name:	Osia System
Classification Name:	Active implantable bone conduction hearing system 21 CFR 874.3340, Class II
Classification Panel:	Ear, Nose, and Throat
Product Code:	PFO
510(k):	K240155

E. Reference Device

Device Names:	Cochlear™ Baha® 7 Sound Processor Cochlear™ Baha® Fitting Software 7 Cochlear™ Baha® Smart App
Trade/Proprietary Name:	Cochlear™ Baha® 7 Sound Processor Cochlear™ Baha® Fitting Software 7 Cochlear™ Baha® Smart App
Common/Usual Name:	Baha 7 Sound Processor Baha Fitting Software 7 Baha Smart App
Classification Name:	Hearing Aid, Bone Conduction 21 CFR 874.3302, Class II
Classification Panel:	Ear, Nose, and Throat
Product Code:	LXB
510(k):	K250215

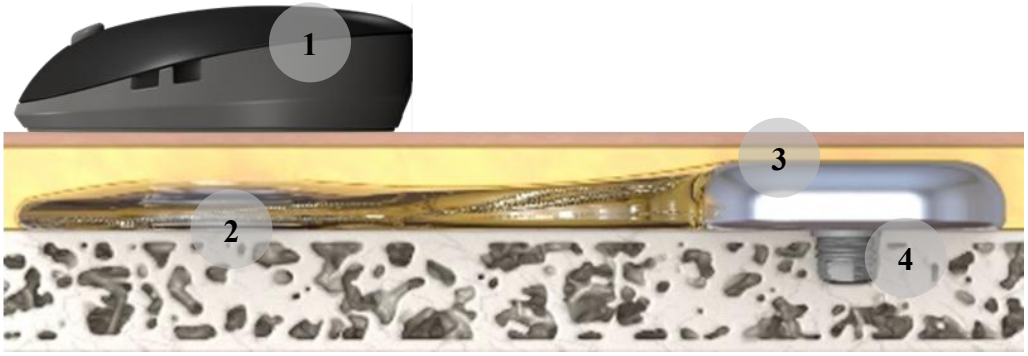
F. Purpose of Submission

This Traditional 510(k) seeks clearance for the addition of the Osia 3/3(I) Sound Processor to the series of sound processors offered by Cochlear. The Osia 3/3(I) 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 Osia 3/3(I) Sound Processor, this 510(k) seeks clearance for new Osia 3/3(I) Sound Processor cover units, updated Osia 3/3(I) Sound Processor magnets, the Osia 3 Charger (to charge the Osia 3/3(I) sound processor), Osia 3 Aqua+ (to enable participation in water activities while wearing the Osia 3/3(I) sound processor), Osia Fitting Software 3 (software that is necessary to program the Osia 3/3(I) Sound Processor) the Osia Smart App (a smart phone application that allows recipients to monitor and control their sound processor).

G. Device Description

The Osia System is made up of several components. The Osia Implant consists of a receiver/coil and an actuator/stimulator (vibrator) which is surgically implanted on the skull bone. The external component of the Osia System is a sound processor, worn off-the-ear, which picks up the sound from the environment, and sends, after processing, the information to the implant via a transcutaneous inductive link. This link is also referred to as radiofrequency (RF) link. Each Osia System is configured to meet an individual's hearing needs, using dedicated fitting software. The Osia System is illustrated in **Figure 1** below.

Figure 1. Osia System, including the Implant and Osia Sound Processor



In normal operation, the Osia System functions as follows (referring to **Figure 1**):

1. The external sound processor captures and digitally processes sound.
2. The sound processor transmits power and digital information to the implant via an RF link.
3. The implant electronics convert the digital information into an electric analog signal.
4. This electric analog signal drives the actuator to produce vibrations, which are transmitted to the skull bone through the BI300 Implant (K100360).

The actuator converts the electrical signal into an amplified mechanical stimulation, bypassing the impaired middle ear (origin of the conductive part of the hearing loss) and providing some level of mechanical amplification in order to compensate for the damaged inner ear (sensorineural part of the hearing loss, in case of mixed hearing loss).

The Osia 3/3(I) Sound Processor includes updated firmware and hardware, including a rechargeable battery, compared to the previously cleared Osia 2/(I) Sound Processor (K231204). The changes introduced in this 510(k) are specific to the sound processor and accessories, and do not affect the cleared Osia implants or the BI300 titanium implant. The Osia 3/3(I) Sound Processor does not modify the intended functionality or fundamental operating principles of the bone conduction hearing system. The changes culminate as the next generation Osia sound processor that supports Bluetooth LE Audio streaming, which enables compatibility with the new generation wireless accessories from GN Hearing, and provides recipients with mixed hearing loss up to 65 dB (sensorineural hearing component) access to sound

The Osia 3/3(I) Sound Processor will be supported by updated retention (Osia 3/3(I) Sound Processor Magnets), updated cover units (Osia 3/3(I) Sound Processor Color Covers), a new

charger (Osia 3 Charger), updated water protection accessory (Osia 3 Aqua+), fitting software (Osia Fitting Software 3), and an updated app (Osia Smart App).

H. Intended Use

The Cochlear Osia System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing. The Osia sound processor is intended to be used as part of the Cochlear Osia System. The sound processor picks up surrounding sound and transfers it to the implant through a digital inductive link.

I. Indications for Use

The Cochlear Osia System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing. The Osia sound processor is intended to be used as part of the Cochlear Osia System. The sound processor picks up surrounding sound and transfers it to the implant through a digital inductive link.

The Osia System is intended for the following patients and indications:

- Patients 5 years of age or older.
- Patients who have a conductive or mixed hearing loss and still can benefit from sound amplification:
  - When used in combination with the Osia 3/3(I) Sound Processor: Bone conduction (BC) thresholds up to 65 dB HL (*Fig. 2*).
  - When used in combination with prior generation Osia sound processors or OSI100 Implant: The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 55 dB HL.
- Bilateral fitting of the Osia System is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies.
- Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., single-sided deafness or "SSD"). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- The Osia System 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.
- Prior to receiving the device, it is recommended that an individual have experience with appropriately fitted air conduction or bone conduction hearing aids.

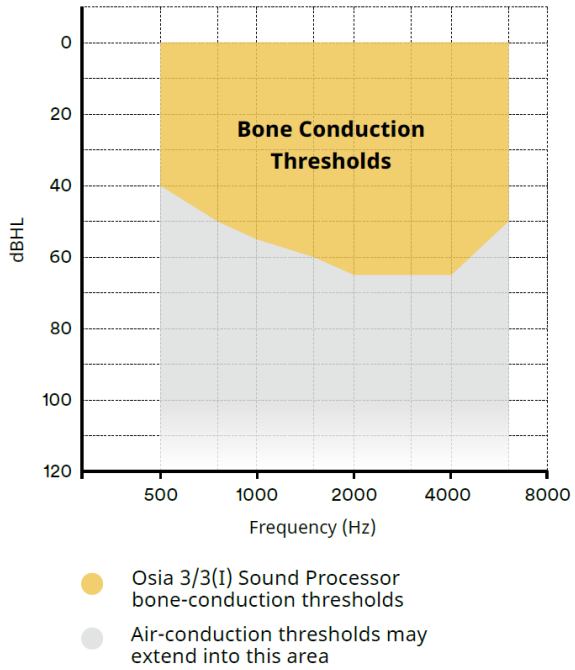


Fig 2: Range of individual bone conduction thresholds covered by the Osia System in combination with the Osia 3/3(I) Sound Processor

Contraindications

- Insufficient bone quality or quantity to support implantation of both the BI300 Implant and the OSI300 Implant
- Chronic or non-revisable vestibular or balance disorders that could prevent benefit from the device, as determined by good clinical judgment
- Abnormally progressive hearing loss
- Evidence that hearing loss is bilateral retrocochlear or bilateral central origin
- Evidence of conditions that would prevent good speech recognition potential as determined by good clinical judgment
- Skin or scalp conditions that may preclude attachment of the Sound Processor or that may interfere with the use of the Sound Processor.

J. Technological Characteristics and Comparison to Predicate

The Osia 3/3(I) 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.

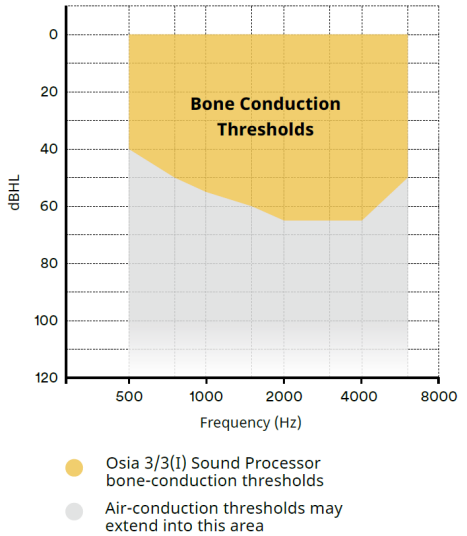
The modified sound processor is compatible with the cleared OSI100 (K190589), OSI200 HWv1 (K191921), OSI200 HWv2 (K220922), and OSI300 (K231204) implants.

The primary modifications to the Osia 3/3(I) Sound Processor relate to updated fitting range, increased connectivity, improved bandwidth, improved sound processing algorithms, and the rechargeable battery.

Table 1 summarizes a comparison of the features, functions, and performance data for the Osia 3/3(I) Sound Processor and the Osia 2/2(I) Sound Processor (Predicate device system).

Table 1: Osia 2/2(I) Sound Processor and the Osia 3/3(I) Sound Processor Comparison Summary

Characteristic	Osia 2/2(I) Sound Processor	Osia 3/3(I) Sound Processor
Indications for Use	The Osia System is intended for the following patients and indications: • Patients 5 years of age or older. • Patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 55 dB HL. • Bilateral fitting of the Osia System is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies. • Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., single-sided deafness or "SSD"). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz). • The Osia System 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. • Prior to receiving the device, it is recommended that an individual have	The Osia System is intended for the following patients and indications: • Patients 5 years of age or older. • Patients who have a conductive or mixed hearing loss and still can benefit from sound amplification: - When used in combination with the Osia 3/3(I) Sound Processor: Bone conduction (BC) thresholds up to 65 dB HL (*Fig. 3*). - When used in combination with prior generation Osia Sound Processors or OSI100 Implant: The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 55 dB HL. • Bilateral fitting of the Osia System is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies. • Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., single-sided deafness or "SSD"). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz). • The Osia System for SSD is also indicated for any patient who is indicated for an air

Characteristic	Osia 2/2(I) Sound Processor	Osia 3/3(I) Sound Processor
	experience with appropriately fitted air conduction or bone conduction hearing aids.	conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS. • Prior to receiving the device, it is recommended that an individual have experience with appropriately fitted air conduction or bone conduction hearing aids.  *Fig 3: Range of individual bone conduction thresholds holds covered by the Osia System in combination with the Osia 3/3(I) Sound Processor* Similar, the indications are still intended to treat the same targeted patient population. The changes enable surgeons and qualified medical professionals to compare patient audiograms directly with the fitting range displayed in device datasheets without requiring

Characteristic	Osia 2/2(I) Sound Processor	Osia 3/3(I) Sound Processor
		PTA4 calculation. This also provides greater transparency to healthcare professionals regarding technical capabilities of the devices, enabling the HCP to better identify appropriate patients for the Osia System.
System compatibility	OSI100 (K190589), OSI200 HWv1 (K191921), OSI200 HWv2 (K220922), and OSI300 (K231204)	Osia 3/3(I) Sound Processor has the same system compatibility
	Made for iPhone Hearing Device ASHA protocol for compatible Android Phones	Similar – Osia 3/3(I) has increased compatibility with Bluetooth LE Audio, compatibility with mFI v2, and direct Android Streaming
	Compatible with accessories that use the GN Hearing Wireless communications protocol	Similar – Osia 3/3(I) introduced support for full functionality with the new Wireless Accessories, the TVStreamer+ and Multi-Mic
Sound Processor Function	The Osia System requires the use of an externally worn sound processor that is worn on the head behind the ear. The Osia 2/2(I) Sound Processor's main function is to receive sound using its two microphones, perform signal processing and deliver power and an audio stream to the implant via the RF link.	Same, for the Osia 3/3(I) Sound Processor.
Sound Processor Magnet	Osia 2 Sound Processor uses standard axial magnets (M1, M2, M3, M4) that are compatible with the OSI100 and OSI200 implant magnets. Osia 2(I) Sound Processor uses diametric magents (1(I), 2(I), 3(I), 4(I)) that are compatible with OSI300 implant magnets.	Similar, both axial and diametric magnets have been updated to interface with the sound processor from the bottom of the sound processor, rather than under a top cover, as used in the Osia 2/2(I) Sound Processor. Magnet strengths have also been updated to range from 1M to 5M and 1(I) to 5(I).

Characteristic	Osia 2/2(I) Sound Processor	Osia 3/3(I) Sound Processor
Sound Procesor Firmware Platform	Dooku2 (Xidium)	Dooku3 (Rhodium)
Contact and Biocompatibility of Sound Processor	The Osia 2/2(I) Sound Processor is an intact-skin contacting device for permanent use. Testing was completed on the sound processor outer materials to demonstrate biocompatibility in accordance with ISO / EN ISO 10993-1: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.	Same, for the Osia 3/3(I) Sound Processor.
Shelf Life and Packaging - Sound Processor	The Osia 2 Sound Processor is not provided in sterile packaging and does not have a restricted shelf life.	The Osia 3/3(I) Sound Processor is not provided in sterile packaging and has a shelf life of 2 years.
Color Covers	Available in five basic colors: • Black • Chocolate Brown • Sandy Blonde • Silver Grey • Slate Grey	Available in the same five basic colors. New color options added: • Arctic Blue • Light Pink • Lavender • Mint • Petrol • Teal
IP Rating	Osia 2/2(I) Sound Processor has IP52 rating	Improved, Osia 3/3(I) Sound Processor has IP68 rating
Sound Processor Battery	Disposable PR44 Zn-Air battery (high power)	New, the rechargeable internal Li-Ion battery is designed to last at least a full day (>16 h). Recharged in Osia 3 Charger.
Sound Processor Dimensions	36 x 32 x 10.4 mm	Similar, 35.5 x 32.1 x 11.2 mm
Sound Processor Weight	• 9.4 g including Zn-Air battery and the smallest SP magnet	• 10.8 g including smallest SP magnet • 14.1 g including heaviest SP magnet

Characteristic	Osia 2/2(I) Sound Processor	Osia 3/3(I) Sound Processor
	• 11.7 g including Zn-Air battery and the heaviest SP magnet	
Basic Signal and Processing Features	4 user-defined programs, which may use dedicated listing programs for everyday, outdoor, noise, and music	Similar, the programs now use LE audio
	Directionality	Same
	No Low Power Program	New, low power program added
	Broadband MPO limits the output power for a broadband signal at very high gain and/or very loud sounds	Similar, improved sound quality at loud output.
	2.4 GHz wireless technology	The Osia 3/3(I) SP supports additional technology: LE Audio for streaming of audio from smart phones and the wireless accessories to Osia 3/3(I) Sound processors BLE based protocol Auracast for streaming of audio from Auracast transmitters
	Scene Classifier	Same
	Wired fitting for initial session using HiPro2. Wireless Fitting available for follow up sessions	Improved, fitting is now fully entirely wireless
	No Impulse Noise Control	Osia 3/3(I) Sound Processor offers Impulse Noise Control, which reduces the volume of sudden loud sounds.
	Feedback suppression	Similar, improved feedback manager
	Datalogging available	Similar, improved to include data on the implant connection
Remote Firmware Upgrade	N/A	Remote Firmware Upgrade is available through the Osia Smart App
Software	Osia Fitting Software 2	Osia Fitting Software 3
	Osia Smart App v1.1	Osia Smart App v1.2

This 510(k) submission also includes the Osia Fitting Software 3 and Osia Smart App. The predicate device for Osia Fitting Software 3 is Osia Fitting Software 2, which is used to program the previous generation of Osia sound processors. The predicate device for the Osia Smart App is the previous version of the Osia Smart App, which is used with the previous generation of Osia sound processors. The updated version of the Osia Smart App contains features that are present in the reference device, the Baha System (K250215). The Osia Fitting Software 3 and Osia Smart App are compared to their respective predicate and reference devices in **Table 2** and **Table 3**, respectively.

Table 2: Osia Fitting Software 2 and Osia Fitting Software 3 Comparison Summary

Feature	Osia Fitting Software 3 compared to Osia Fitting Software 2
Visualization and warning of rechargeable battery level	New, introduced to support the rechargeable battery in the Osia 3/3(I) sound processor.
Login and Audit trail	Existing
Patient information	Existing
Audiogram	Existing
BC Select – patient background-based fitting	Existing
BC direct in-situ measurement	Existing
Digital link calibration	Existing
Feedback Analyser measurement	Existing
Feedback Manager	Existing
Hearing mentor	Existing
Fine tuning	Existing
Program settings	Existing
Datalogging	Existing
Active gain	Existing
Set up wireless options	Existing
Session report	Updated, the HCP can add or exclude information in the report by choosing from a checklist
Up to 4 listening programs	Existing
Guided workflow	Existing
Compatible with Noah	Existing
Wireless programming	Updated, OFS 3 enables for all programming to be completed wirelessly using Noahlink Wireless. OFS 2 required HiPro2 to be used for initial fitting, and Noahlink Wireless could only be used for follow up fittings.

Feature	Osia Fitting Software 3 compared to Osia Fitting Software 2
Setup replacement sound processor	Existing
Training mode/Simulation mode	Existing
FW upgrade that saves initial fitting	Existing
Implant Integrity Test	Existing
Remote Assist	New, enables the healthcare professional (HCP) to perform fitting sessions with Osia Fitting Software 3 with a Recipient remotely without requiring the Recipient to be physically present at the clinic. The App provides a video, chat, and audio interface for the Recipient to interact with the HCP during a remote session. The HCP can make the necessary adjustments to the sound processor and permanently store the configuration to the sound processor.
Forward Focus	New, gives the recipient or carer the ability to modify an Everyday or Noise program into Forward Focus mode.
Low power program	New, a program type that allows the OSI implant to operate at a lower voltage to save power and enhances sound processor battery autonomy.
Extended audio bandwidth	New, provides clinicians the ability to select between High Bandwidth and Low Bandwidth, where the latter would give the same bandwidth as Osia 2/2(I) SP.
Impulse Noise Reduction	New, provides clinicians the ability to select the aggressiveness of the reduction of noise from sudden impulses

Table 3: Osia Smart App Comparison Summary

Feature	Comparison of Osia Smart App v1.2 to v1.1
Account Creation	Existing
Customer Login	Existing
Guided connect	Existing
Remote Assist	New, enables the Healthcare Provider to perform fitting sessions with Osia Fitting Software 3 with a Recipient remotely without requiring the Recipient to be physically present at the clinic. The App provides a video, chat, and audio interface for the Recipient to interact with the Healthcare provider during a remote session. The Healthcare Provider can make the necessary adjustments to the sound processor and permanently store the configuration to the sound processor. This functionality is implemented in the same way that is currently cleared in the reference device, the Baha System (K250215).

Feature	Comparison of Osia Smart App v1.2 to v1.1
Activate Streaming and adjust volume - Wireless Accessories	Updated to include support for Gen3 Wireless Accessories
Adjust Volume and mute	Existing
Change Program	Existing
Equalizer	Existing
Noise Reduction and Impulse Noise reduction	New, gives the recipient the ability to modify Noise Reduction and Impulse Noise Reduction for Everyday, Noise, Music and Outdoor programs. This is inherited from the currently cleared reference device, the Baha System (K250215).
Set Forward Focus	New, gives the recipient or carer the ability to modify an Everyday or Noise program into Forward Focus mode.
Create Favourites	Existing
Sound Processor Status	Existing
Apple Watch Support	Existing
Datalog	Existing
Simulate Signals	Existing
Locate lost sound processor	Existing
Remote sound processor firmware update	New, enables the recipient the ability to update the firmware on the Sound Processor via the Smart App.
Connection status SP to Implant	New, provides a live indication of connection status to implant when connected to Osia 3/3(I) Sound Processor.
Sound processor registration	Existing
Self-managed account management	Existing
Walkme (webservice that enables in-app communication to users, such as surveys)	Existing

K. Performance Data

Testing of the Osia 3/3(I) Sound Processor and components included biocompatibility, software, electromagnetic compatibility, bench testing, and clinical 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 Osia Fitting Software 3 and Osia Smart App. The testing demonstrated that the software supported the clinician fitting and recipient control of the Osia 3/3(I) 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 Osia 3/3(I) SP does not result in additional safety or effectiveness concerns in comparison to the predicate.
- Clinical data from the pivotal study included speech perception testing as well as patient reported outcomes. Ten subjects had at least one bone conduction threshold greater than 55 dB HL in the implanted ear. All subjects demonstrated clinically meaningful benefit with the Osia 3/3(I) device, as indicated in the word recognition scores (WRS) in quiet, speech reception threshold (SRT) in noise and sound field threshold PTA4.

The results demonstrate the Osia 3/3(I) Sound Processor is functionally equivalent to the Osia 2/2(I) Sound Processor.

L. Conclusion

Based on the indications for use, technological characteristics, substantial equivalence comparison to the predicate device, and performance data, the Osia 3/3(I) Sound Processor and components has been shown to be as safe and as effective for its intended use.