April 18, 2024

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

Re: K240155
Trade/Device Name: Cochlear Osia System
Regulation Number: 21 CFR 874.3340
Regulation Name: Active Implantable Bone Conduction Hearing System
Regulatory Class: Class II
Product Code: PFO
Dated: January 19, 2024
Received: January 19, 2024

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 (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.

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
OHT1: Office of Ophthalmic, Anesthesia,
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240155

Device Name
Cochlear™ Osia® System

Indications for Use *(Describe)*
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 experience with appropriately fitted air conduction or bone conduction hearing aids.

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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K240155 - 510(k) Summary

A. Submitter Information

Submitted by:

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Lone Tree, CO 80124

On behalf of the manufacturer:

Cochlear Ltd – Macquarie
1 University Avenue
Macquarie University, NSW 2109
Australia
(Establishment Number 3009092818)

Contact:

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Cochlear Americas
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B. Date Prepared

19-January-2024

C. Device Name and Classification

Device Names:

Cochlear™ Osia® OSI300 Implant
Cochlear™ Magnet Cassette
Cochlear™ Non-Magnetic Cassette
Cochlear™ Osia® 2(I) Sound Processor

Cochlear™ Osia® OSI200 Implant
Cochlear™ Sterile Replacement Magnet
Cochlear™ Sterile Non-Magnetic Plug
Cochlear™ Osia® 2 Sound Processor

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

D. Predicate Device

Device Names:	Cochlear™ Osia® OSI300 Implant Cochlear™ Magnet Cassette Cochlear™ Non-Magnetic Cassette Cochlear™ Osia® 2(I) Sound Processor Cochlear™ Osia® OSI200 Implant Cochlear™ Sterile Replacement Magnet Cochlear™ Sterile Non-Magnetic Plug Cochlear™ Osia® 2 Sound Processor 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):	K231204

E. Purpose of Submission

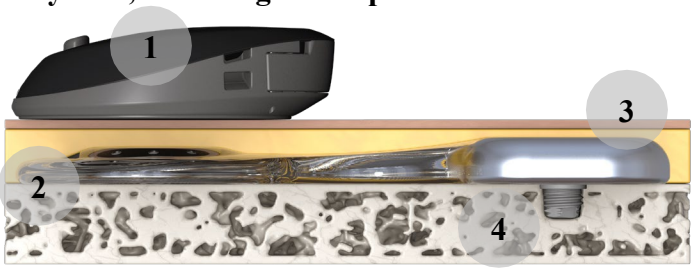
This Traditional 510(k) seeks clearance for an updated pediatric indication for the Osia System. The previous Osia System was cleared under K231204 on August 18, 2023.

F. Device Description

The Osia System mechanically vibrates the skull bone and subsequently the cochlea to compensate for conductive hearing loss, mixed hearing loss, or single-sided sensorineural deafness (SSD).

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).

This change for the Osia System introduces an expanded indication from 12 years of age or older to 5 years of age or older.

G. Intended Use

The Cochlear Osia System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing.

The OSI300 Implant or OSI200 Implant is intended to be used as part of the Cochlear Osia System to convert information from the external Sound Processor into mechanical vibrations.

Osia single-use and reusable surgical instruments are used throughout the surgery to correctly position and attach the Osia implant.

H. 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 experience with appropriately fitted air conduction or bone conduction hearing aids.

I. MR Conditional

The Osia System's OSI300 implant is designed to allow the patient to be examined by an MRI at 1.5T and at 3T without having the implant magnet removed or required use of an MRI kit.

The Osia System's OSI100 and OSI200 implants are MR conditional with the implant magnet in place with the use of a Cochlear MRI Kit at 1.5T or with the magnet removed at 1.5T and 3.0T. The MRI Kit is intended to prevent the dislodgement of implanted magnets in a hearing implant during a Magnetic Resonance Imaging (MRI) procedure.

The MRI Kit is indicated for hearing implant recipients who require an MR scan at 1.5T and have been assessed by medical professionals as suitable for an MR scan.

The MRI Kit is indicated for a recipient with the following compatible Osia implants:

- Osia OSI100 implant
- Osia OSI200 implant

J. Technological Characteristics and Comparison to Predicate

Like other active implantable bone conduction hearing systems, the Osia System is comprised of multiple components, including: an implant, sound processor, fitting software, and other cables and accessories. The Osia System is intended to compensate for conductive or mixed hearing loss or single sided deafness by conveying amplified acoustic signals to the cochlea via mechanical vibrations on the skull bone. These vibrations bypass the damaged parts of the outer and/or middle ear to stimulate the inner ear hair cells, allowing patients to clearly hear sounds and speech around them.

The Osia System with expanded indications and the predicate Osia System are identical systems. There are no changes to the devices within the system. which are surgically implanted in the mastoid bone, and an external sound processor is held in place on the patient's scalp by magnetic attraction between the implant and sound processor.

Table 1 summarizes a comparison of the technological characteristics of the currently available Osia 2 System (predicate device) with the updated Osia System (subject device).

Table 1: Comparison Summary of Osia System

Technological Characteristic	Osia System (Predicate, K231204)	Osia System (Subject)
Intended Use	The Cochlear Osia System uses bone conduction to transmit sounds	Same

Technological Characteristic	Osia System (Predicate, K231204)	Osia System (Subject)
	to the cochlea (inner ear) with the purpose of enhancing hearing. The OSI300 Implant or OSI200 Implant is intended to be used as part of the Cochlear Osia System to convert information from the external Sound Processor into mechanical vibrations. Osia single-use and reusable surgical instruments are used throughout the surgery to correctly position and attach the Osia implant.	
Indications	The Osia System is intended for the following patients and indications: • Patients 12 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	Expanded to include Patients 5 years of age or older.

Technological Characteristic	Osia System (Predicate, K231204)	Osia System (Subject)
	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.	
Energy Used / Delivered	An external sound processor is used to pick up surrounding sound and transfer it to an implant through a digital inductive link. That implant picks up the signal and translates it into vibrations. A second implant is screwed into the bone (and osseointegrates), and is attached to the first implant, ensuring implant anchoring and that vibrations are transferred to the cochlea.	Same
System Compatibility	The Osia System includes an implant, sound processor, surgical tools and accessories, software, programming cable, and fitting software. It is also capable of wireless connection to accessories and fitting software.	Same
Implant	OSI300 or OSI200 Implant	Same
Osseointegrated Implant	BI300 (K100360)	Same
Biocompatibility of Implant	Biocompatibility of the Osia System has been evaluated and tested. All tests were passed and	Same

Technological Characteristic	Osia System (Predicate, K231204)	Osia System (Subject)
	confirm that the Osia System is biocompatible. The Osia implants were assessed as biologically safe in accordance with ISO 10993-1:2018, ISO 14708-7:2013, and the FDA Guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation of testing within a risk management process" (2016), for a permanent (>30 days) implant device contacting tissue and bone and can be considered safe for use.	
Sterilization of Implant	Each Osia Implant is delivered ethylene-oxide (EO) sterilized and packed into protective packaging. Sterilization validation was demonstrated to be in compliance with ISO 11135: 2014.	Same, the sterilization method remains the same.
Shelf Life and Packaging-Implant	Shelf-life of the Osia Implant is 2.5 years. The packaging of the implant was designed and validated to ensure the sterility and integrity of the individually packaged and sealed devices during sterilization, distribution and storage over the labeled shelf life according to EN 45502-1 Cl. 12.1 and compliance with EN ISO 1160711607 – 2009 +A1:2014.	Same, the shelf life remains the same.
Implant Reliability Testing and Non-Clinical Performance Data	The verification tests for performance and reliability of the Osia Implants include those related to: Acoustic Output, Link Integrity, Fixation Screw, Static Load, Coil Impact, Cyclic Load, Static Load, Lifetime Testing, Hermeticity, Coil Robustness, Fluid Ingress, Particulate Matter Testing,	Same, the results of bench testing of each implant remains unchanged with the indication change.

Technological Characteristic	Osia System (Predicate, K231204)	Osia System (Subject)
	Maximum Surface Temperature, and Environmental Conditioning.	
Clinical Data	Clinical data was gathered to determine the safety and effectiveness of the Osia system in children ages 5-11. Safety was demonstrated through the reports of adverse events related to the device and procedure being similar to those experienced by the population identified by the predicate indications for use with this device. Effectiveness was demonstrated by both patient-reported outcomes by the participants' parent as well as through improved speech intelligibility in both quiet and noise.	
MRI Compatibility	The Osia System is MR Conditional.	Same, the Osia System remains MR Conditional. The MR Conditions have not changed as a result of the expanded indication.
Sound Processor	Osia 2 Sound Processor and Osia 2(I) Sound Processor	Same, the compatible sound processors remain unchanged.
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 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 Osia implant via the RF link.	Same, the sound processor function remains unchanged.
Sound Processor Magnet	The Osia 2 Sound Processor uses standard axial magnets that are compatible with the OSI100 and OSI200 implant magnets. The Osia 2(I) Sound Processor uses imaging magnets with diametric polarization that are compatible with the OSI300 implant magnet.	Same, the compatible sound processor magnets remain unchanged.
Sound Processor Firmware	The Osia 2 Sound Processor chipset includes two distinct blocks: one block is based on the GN Hearing	Same, the sound processor firmware is

Technological Characteristic	Osia System (Predicate, K231204)	Osia System (Subject)
	C4.5/Palpatine platform, and is responsible for receiving the microphone input, performing signal processing, and delivering an analogue output signal that is fed into the differential input of the other block, the NEO-XS chip. The NEO-XS block is responsible for transferring the audio signal to the implant via the RF link.	not impacted by the expanded indication.
Contact and Biocompatibility of Sound Processor	The Osia 2 Sound Processor and Osia 2(I) Sound Processor are intact-skin contacting devices for permanent use. Testing was completed on the sound processor outer materials to demonstrate biocompatibility in accordance with ISO / EN ISO 10993-1: October 2009 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.	Same, the contact and biocompatibility of the sound processor remains unchanged.
Shelf Life and Packaging - Sound Processor	The Osia 2 Sound Processor and Osia 2(I) Sound Processor are not provided in sterile packaging and do not have a restricted shelf life.	Same
Fitting Software	The Osia Fitting Software 2 is used by the audiologist to configure all patient related data in the sound processor. The fitting software is an application running on a Windows PC. It is a stand-alone software.	Same, the fOsia Fitting Software 2 is not impacted by the expanded indication change.
Smart App	The Osia Smart App is a software application intended to remotely control and monitor the Osia 2 Sound Processor directly from a smartphone. Available for Android and iOS.	Same, the Osia Smart App is not impacted by the expanded indication change.

As required by the Special Controls identified for this device type, a summary of the clinical data

is provided in the product labelling.

K. Clinical Performance Data

A pivotal, prospective, multi-center study that uses each participant as their own control was performed to determine the safety and effectiveness of the Osia system in children ages 5-11 and demonstrate substantial equivalence of the expanded indications for use to the cleared indications for use.

The primary objective was to demonstrate safety by quantifying the type, frequency, and severity of adverse events.

Secondary effectiveness objectives included:

- To compare preoperative performance compared to postoperative performance in parental questionnaires (SSQ) using the Osia System.
- To compare preoperative unaided bone conduction thresholds to postoperative unaided bone conduction thresholds.
- To compare unaided preoperative speech perception performance in quiet to aided speech perception performance postoperatively using the Osia System.
- To compare unaided preoperative adaptive speech in noise performance to aided adaptive speech in noise performance using the Osia System.

The results demonstrate that adverse events and safety considerations for the expanded indication remain consistent with adverse events for individuals ages 12 and older. Additionally, children ages 5-11 implanted with the Osia System demonstrate significant improvement in quality of life as evidenced in parental questionnaires and in speech perception as evidenced in testing in quiet and in adaptive noise. These results provide objective evidence that the Osia System is effective in an expanded pediatric population.

L. Conclusion

Based on the technological characteristics, substantial equivalence comparison to the predicate device, and the indications for use, supported by clinical data, the change to expand the pediatric indications for use of Cochlear Osia System has been shown to be as safe and effective for its intended use as the cleared indications for the predicate Osia System.