July 27, 2022

Cochlear Americas
Samata Veluvolu
Principal Regulatory Specialist
10350 Park Meadows Drive
Lone Tree, Colorado 80124

Re: K220922
Trade/Device Name: Cochlear Osia 2 System, Cochlear Osia OSI200 Implant, Cochlear Osia 2 Sound Processor, Cochlear Osia Fitting Software 2, Cochlear MRI Kit
Regulation Number: 21 CFR 874.3340
Regulation Name: Active implantable bone conduction hearing system
Regulatory Class: Class II
Product Code: PFO
Dated: June 23, 2022
Received: June 24, 2022

Dear Samata Veluvolu:

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)*
K220922

Device Name
Cochlear™ Osia® 2 System

Indications for Use *(Describe)*
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 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 airconduction 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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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 9076254)
Contact:	Samata Veluvolu Principal Regulatory Specialist Cochlear Americas C: 302-542-6468 E: sveluvolu@cochlear.com

B. Date Prepared

26-July-2022

C. Device Name and Classification

Device Names:	Cochlear™ Osia® OSI200 Implant Cochlear™ Osia® 2 Sound Processor Cochlear™ Osia® Fitting Software 2 Cochlear™ MRI Kit
Trade/Proprietary Name:	Cochlear™ Osia® 2 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® OSI200 Implant Cochlear™ Osia® 2 Sound Processor Cochlear™ Osia® Fitting Software 2
Trade/Proprietary Name:	Cochlear™ Osia® 2 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):	K191921

E. Purpose of Submission

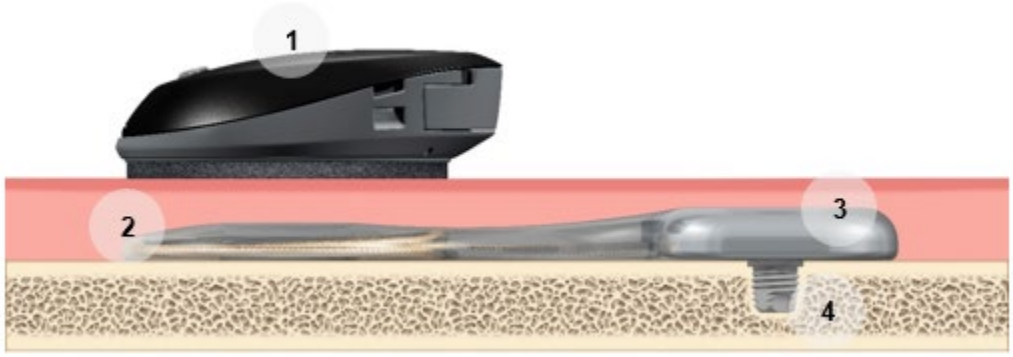
This Traditional 510(k) seeks clearance for an updated Osia 2 System, which includes modifications to existing Osia 2 System components (the OSI200 Implant, Osia 2 Sound Processor and Osia Fitting Software 2) and requests clearance of a Cochlear MRI Kit accessory for use by Osia recipients. The second generation Osia System, Osia 2 System (predicate), was cleared under K191921 on November 15, 2019.

F. Device Description

The Osia 2 System, also known as 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 2 System is made up of several components. The Osia implant (OSI200) consists of a receiver/coil and an actuator/stimulator (vibrator) which is surgically implanted on the skull bone. The external component of the Osia 2 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 2 System is configured to meet an individual's hearing needs, using dedicated fitting software. The Osia 2 System is illustrated in **Figure 1** below.

Figure 1. Overview of the Osia 2 System, including the Osia 2 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 coil/receiver.

3. The implant stimulator/actuator converts the digital information into an electric analogue signal that is converted to vibrations by the implant piezoelectric actuator.
4. This implant is fixed to the bone by 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 updated Osia 2 System consists of modifications to the cleared OSI200 Implant, Osia 2 Sound Processor and Osia Fitting Software 2. All other components of the system remain unchanged from the cleared predicate.

The Cochlear MRI Kit is being introduced for use by Osia recipients. The MRI Kit is an accessory that enables an MR scan at 1.5T without the need to surgically remove a compatible Osia implant's magnet.

G. Intended Use

The Cochlear Osia System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing. Osia Implants are single use devices intended for long term implantation under the skin in the mastoid region of either side of the head. They are for professional use only.

H. Indications for Use

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 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 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 2 System is comprised of multiple components, including: an implant, sound processor, fitting software, and other cables and accessories. The Osia 2 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.

Both the updated Osia 2 System and the predicate Osia 2 System 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.

The updated Osia 2 System, which includes modifications to the cleared OSI200 Implant, Osia 2 Sound Processor and Osia Fitting Software 2, has the same intended use, the same overall functional characteristics, and the same fundamental operating principles as the predicate Osia 2 System. The updated Osia System introduces the MRI Kit as a new accessory for use with compatible Osia implants.

Table 1 summarizes a comparison of the technological characteristics of the currently available Osia 2 System (predicate device) with the updated Osia 2 System (subject device). Additional details related to the changes are provided below the table.

Table 1: Comparison Summary of Osia 2 System

Technological Characteristic	Osia 2 System (Predicate, K191921)	Osia 2 System (Subject)
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	Same

Technological Characteristic	Osia 2 System (Predicate, K191921)	Osia 2 System (Subject)
	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.	
System Compatibility	The Osia 2 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 the fitting software.	The Osia 2 System has the same system compatibility with the addition of the Cochlear MRI Kit.
OSI200 Implant	The OSI200 Implant consists of the following major components: fixation screw, lead/coil, actuator, stimulator, and magnet.	Same, except the OSI200 Implant's printed circuit assembly (PCA) has been updated.
Osseointegrated Implant	BI300 (K100360)	Same
Radiation Safety	The Osia System is compatible for use with x-ray, CT scans, radiation therapy, and PET. The Osia System is MR Conditional.	The Osia System is compatible for use with x-ray, CT scans, radiation therapy, and PET. The Osia System remains MR Conditional; however, MR Conditions have changed to allow MR scans at 1.5T with the implant magnet in place with the use of a Cochlear MRI Kit.
OSI200 Implant magnet conditions for MRI	The OSI200 Implant is MR conditional with the implant magnet removed at 1.5T and 3.0T.	The OSI200 Implant is MR conditional with the implant magnet in place with the use of a Cochlear MRI Kit at 1.5T, or removed at 1.5T and removed at 3.0T.
Sound Processor	The Osia 2 System requires the use of an externally worn sound processor that is worn on the head behind the ear.	Same, except the Osia 2 Sound Processor firmware (for the second block) is updated with new

Technological Characteristic	Osia 2 System (Predicate, K191921)	Osia 2 System (Subject)
	The Osia 2 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 OSI200 implant via the RF link. The Osia 2 Sound Processor chipset includes two distinct blocks: one block 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 second block is responsible for transferring the audio signal to the implant via the RF link.	functionalities to support the changes to the OSI200 Implant.
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, except new features are available in the Osia Fitting Software 2 to support the changes to the OSI200 Implant.

Additional details on the new features and functionalities added to predicate components are provided below:

OSI200 Implant

- The Printed Circuit Assembly (PCA) quantization level setting has been updated.
- A power switch has been enabled to control the implant gain setting to reduce the noise floor, if required.
- New circuitry has been added to improve implant restart time when the implant resets due to power supply being at critical voltages.

Verification related to the OSI200 Implant was completed based on changes to the printed circuit assembly (PCA) and concluded that the PCA does not affect the safety and effectiveness of the device. See **K. Performance Data** for more details on bench testing completed.

Osia Fitting Software 2

- The updated software has the ability to detect the updated OSI200 Implant.
- Additional functionality has been added to activate the implant gain setting feature, if required.

Verification related to the Osia Fitting Software 2 was performed on a series of software builds which confirmed that the new functionalities added to the fitting software to allow it to detect the updated OSI200 implant and activate the gain setting do not affect safety and effectiveness of the device.

Osia 2 Sound Processor

- The updated sound processor has the ability to detect the updated OSI200 Implant.
- Additional functionality has been added to activate the implant gain setting feature, if required.
- Configured sleep mode in sound processor to improve system startup process.

The Osia 2 Sound Processor hardware remains unmodified from the predicate device. Verification results related to the sound processor's firmware confirm that the new functionalities added to the sound processor firmware to allow it to detect the updated OSI200 implant and activate the gain setting do not affect safety and effectiveness of the device.

K. Performance Data

Bench testing was conducted to compare the updated Osia 2 System with the cleared Osia 2 System. Substantial equivalence to the predicate device was accomplished through non-clinical data related to functionality and performance testing, hardware and interface testing, as well as system and subsystem level testing.

Verification activities for the modified OSI200 Implant included performance testing re-executed to support:

- Functional verification
- Safety and Reliability verification related to Accelerated Life, Maximum Surface Temperature, Diagnostic Ultrasound, Therapeutic Ionising Radiation, ESD, High Power Electric Fields
- Environmental Testing verification

The following verification testing performed on the cleared OSI200 Implant remains applicable to the modified OSI200 Implant and were leveraged with justification from the predicate device.

- Fixation Screw verification
- Safety and Reliability verification related to Static and Cyclic Load, Impact, Robustness, Fluid Ingress, Release of Particulate Matter, Biological Safety, System EMC Compliance, MRI Safety
- Surgical Implementation
- Sterilization
- Sterile Barrier

- Shelf-Life

Validation activities re-executed for the OSI200 Implant were limited to Intended Implant Lifetime. Validation for the Osia 2 System included tests re-executed to validate the functionality and performance of the updated system.

The Cochlear MRI Kit underwent verification testing of the safety of the MRI Kit when used at 1.5T with Osia implants, and underwent summative usability testing to evaluate the usability of the MRI Kit and accompanying documentation by specialized healthcare professionals.

The results demonstrate the updated Osia 2 System, including the modified OSI200 Implant, Osia 2 Sound Processor, and Osia Fitting Software 2 and new Cochlear MRI Kit, are functionally equivalent to the cleared Osia 2 System.

L. Conclusion

Based on the indications for use, technological characteristics, and substantial equivalence comparison to the predicate device, supported by non-clinical data, the updated Cochlear Osia 2 System has been shown to be as safe and as effective for its intended use as the predicate device.