November 15, 2019

Cochlear Americas
Chinda Hemmavanh
Senior Regulatory Affairs Specialist
13059 E Peakview Avenue
Centennial, Colorado 80111

Re: K191921
Trade/Device Name: Cochlear Osia OSI200 Implant, Cochlear Osia 2 Sound Processor, Osia Fitting Software 2.0, Osia SmartApp, Cochlear Osia Surgical Instruments
Regulation Number: 21 CFR 874.3340
Regulation Name: Active implantable bone conduction hearing system
Regulatory Class: Class II
Product Code: PFO
Dated: October 15, 2019
Received: October 16, 2019

Dear Chinda Hemmavanh:

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,

for Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191921

Device Name
Cochlear™ Osia™ 2 System

Indications for Use *(Describe)*

The Osia 2 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 2 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 2 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K191921

A. Submitter Information

Submitted by:
Cochlear Americas
13059 East Peakview Ave.
Centennial, CO 80111

On behalf of the manufacturer:
Cochlear Ltd – Macquarie
1 University Avenue
Macquarie University, NSW 2109
Australia
(Establishment Number 9076254)

Contact:
Chinda Hemmavanh, Ph.D
Senior Regulatory Affairs Specialist
Cochlear Americas
chemmavanh@cochlear.com
(303) 264- 2318 (o)
(303) 524-6825 (f)

B. Date Prepared

16-July-2019

C. Device Name and Classification

Trade/Proprietary Name: Cochlear™ Osia™ 2 System

Common/Usual Name: Osia 2 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

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):	K190589

E. Purpose of Submission

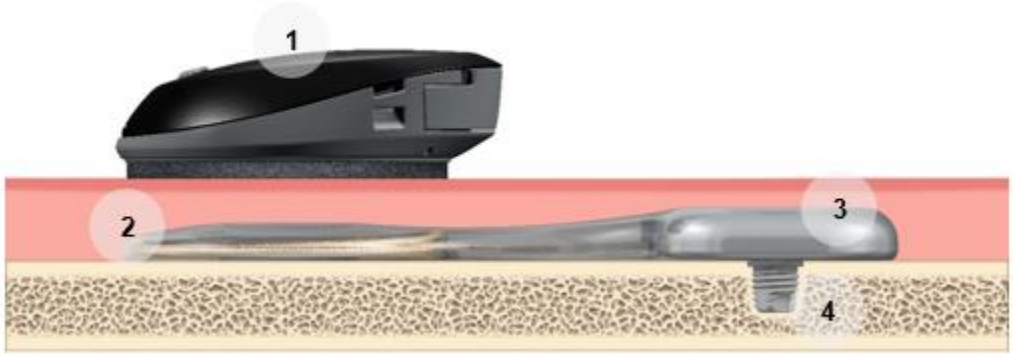
This Traditional 510(k) seeks clearance for an active implantable bone conduction hearing system, known as the Cochlear™ Osia™ 2 System. The Osia 2 System can be used by individuals aged 12 and older with mixed or conductive hearing loss, or single sided deafness to provide improved hearing.

F. Device Description

Cochlear™'s Osia 2 System mechanically vibrates the skull bone and subsequently the cochlea to compensate for conductive hearing loss, mixed hearing loss, or single-sided 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 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 (**Figure1**)

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).

G. Intended Use

The Cochlear Osia 2 System uses bone conduction to transmit sounds to the cochlea (inner ear). Cochlear Osia OSI200 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 2 System is intended for the following patients and indications:

- Patients 12 years of age or older.
- Patients with a conductive or mixed hearing loss who can still benefit from sound amplification. The pure tone average bone-conduction hearing 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 2 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 2 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 2 System OSI200 Implant is MR Conditional with the implant magnet removed at 1.5 T and 3.0 T.

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 Osia 2 System and the predicate, Osia System, are surgically implanted in the mastoid bone and an external audio processor is held in place on the patients scalp by magnetic attraction between the implant and audio sound processor. Below in **Figure 2** is a comparison of the Osia 2 System and the predicate Osia System. **Table 1** summarizes a comparison of the features, functions, and performance data for the Osia 2 System and Osia System (Predicate device system).

Figure 2: Side by Side Comparison of the predicate device, Osia System (left) and the proposed device Osia 2 System (right).

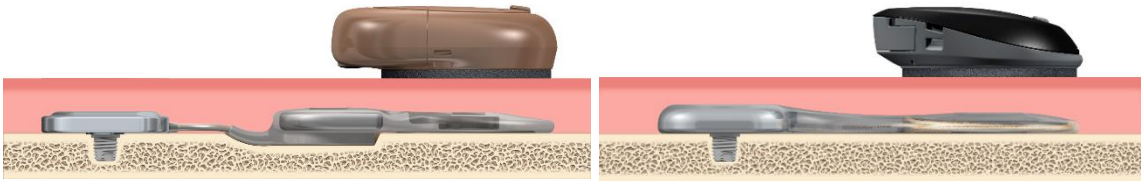


Table 1. Comparison Summary of the Osia 2 System and Osia System (K190589)

Device Component or Technological Characteristic	**Osia System Implant: OSI100 Implant Predicate K190589**	**Osia 2 System Implant: OSI20 Implant Proposed Device**
Implant Receiver Coil	The receiver coil is inductively matched to the coil of the externally worn sound processor. It picks up the signal and conducts the signal to the actuator via a lead.	Same
Implant Actuator	The implant uses a piezoelectric actuator to generate the mechanical vibration that is sent to the patient skull.	Same
Actuator Dampening Pads	The predicate OSI100 Implant does not have dampening pads in the actuator.	The actuator has design has been improved by adding a damping system consisting of eight silicone damping pads to improve shock performance. The addition of the silicone pads does not raise new issue of safety nor effectiveness.
Link between Received Coil and Actuator	The predicate device had a stimulator/coil that received the signal from the sound processor. The signal was then transferred to the piezoelectric actuator via a lead.	The smaller design of the implant does not require a lead. The proposed device has the stimulator-electrical assembly and actuator housed together. The coil is one unit that is attached directly into the stimulator/actuator, and the coil provides the signal that is transferred to the piezoelectric actuator.
Osseointegrated component	The Osia System the is fixed to the bone by the BI300 implant (K100360).	Same

Device Component or Technological Characteristic	**Osia System Implant: OSI100 Implant Predicate K190589**	**Osia 2 System Implant: OSI20 Implant Proposed Device**
Implant and Sound Processor Inductive Link	The Osia System contains an electromagnetic inductive link (also known as radio-frequency link) between the external sound processor coil and the implant coil. The inductive link allows sound data and power to be transmitted to the implant.	Same
Implant Power Source	The stimulator contains dedicated electronics whose power is supplied by the batteries in the external sound processor.	Same
Sound Processor	The Osia System have sound processors that are worn on the head behind the ear and held in place by magnets. Both are powered by standard hearing aid batteries and have multiple color variants.	Same
Sound Processor Wireless Capabilities	The Osia Sound Processor does not have the ability to connect wirelessly with the fitting software nor wireless accessories.	The Osia 2 Sound Processor has an additional ability to connect wirelessly to the Osia Fitting Software 2.0 The Osia 2 Sound Processor can connect to wireless accessories.
Fitting Software Level of Concern	The fitting software platform have a minor level of concern and are used for the same purpose	Same
Fitting Software Features	The Osia Fitting Software 1.0 can set up to 4 programs within a sound processor.	Osia Fitting Software 2.0 (OFS 2.0) can also set up to 4 programs within a sound processor, and has these additional features: • OFS 2.0 interact with two different programming interfaces: Wired Hipro2 and Noah Link wireless

Device Component or Technological Characteristic	Osia System Implant: OSI100 Implant Predicate K190589	Osia 2 System Implant: OSI20 Implant Proposed Device
		• OFS 2.0 can be used to pair wireless accessories • There are more settings and functions in OFS 2.0 (active gain setting, play test tones) • The OFS 2.0 is able to do a factory reset
Implant Reliability Testing and Performance Data	The implant went under performance testing for: Environmental Conditioning, Acoustic, Link Integrity, Maximum Surface Temperature, Coil Robustness, Coil Impact, Static Load, Cyclic Load, Fluid Ingress, Fixation, and Particulate Matter Testing.	Same
Implant Lifetime	Minimum of 6 years	Minimum of 10 years
Osia System Performance Data	The Osia System went under performance testing for: Intra-operability, Compatibility between interfaces, Functional testing, System performance, Safety and Measurement functions.	Same

Osia System EMC Testing	• Electromagnetic Emissions Testing - Radiated Emission
	• Electromagnetic Emissions Testing - Conducted Emission
	• Electromagnetic Emissions Testing –Radiated Emission in Airborne Environment
	• Electromagnetic Immunity Testing - Radiated RF Field (RRFF)- Immunity to Radiated RF EM fields at Enclosure Port
	• Electromagnetic Immunity Testing - Radiated RF Field (RRFF)- Immunity to Proximity Fields from RF Wireless Communications Equipment
	• Electromagnetic Immunity Testing - Radiated RF Field (RRFF)-
	  • EN 45502-2-3 Clauses 27.3 and 27.4
	  • ISO 14708-3 Clauses 27.103 to 27.106
		Same
		Including additional EMC testing to AIM Standard 7351731

Device Component or Technological Characteristic	Osia System Implant: OSI100 Implant Predicate K190589	Osia 2 System Implant: OSI20 Implant Proposed Device
	• Electromagnetic Immunity Testing – Conducted RF disturbance (CRFD) • Electromagnetic Immunity Testing – Exposure to RFID • Static Magnetic Field Immunity Testing	
Implant Contact	The implant is categorised as a permanent (>30 days) implant device contacting tissue and bone, as defined by ISO 10993-1:2018 and EN ISO 10993-1:2009 / AC: 2010.	Same
Implant Material	Direct contacting materials: • Titanium Fixation Screw • Titanium Chassis • Silicone Outer Moulding • Titanium Magnet • Platinum Plate Electrode	Same direct contact materials: • Titanium Fixation Screw • Titanium Chassis • Silicone Outer Moulding • Titanium Magnet Exception: The Osia 2 System implant does not have a platinum plate electrode.
Sound Processor Contact	The sound processor is categorised as a permanent (>30 days) surface device contacting intact skin, as defined by ISO 10993-1:2018 and EN ISO 10993-1:2009 / AC: 2010.	Same
Implant Biocompatibility	Biocompatibility of the device system has been evaluated and tested. All tests were passed and confirm that the system is biocompatible FDA guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued on June 16, 2016. Below are the standards that were verified through testing or justification based on components from currently approved/cleared medical devices.	Same

<table>
<tr><th>Device Component or Technological Characteristic</th><th>Osia System
Implant: OSI100 Implant
Predicate K190589</th><th>Osia 2 System
Implant: OSI20 Implant
Proposed Device</th></tr>
<tr><td></td><td><table>
<tr><th>Test Description</th><th>Standard</th></tr>
<tr><td>Cytotoxicity</td><td>ISO10993-5: 2009</td></tr>
<tr><td>Intracutaneous reactivity/irritation</td><td>ISO10993-10: 2010</td></tr>
<tr><td>Systemic toxicity</td><td>ISO10993-11:2006</td></tr>
<tr><td>Implantation</td><td>ISO10993-6: 2007</td></tr>
<tr><td>Sensitization</td><td>ISO10993-10:2010</td></tr>
<tr><td>Genotoxicity</td><td>ISO10993-3:2014</td></tr>
<tr><td>Subchronic toxicity</td><td>ISO10993-11:2006</td></tr>
<tr><td>Carcinogenicity and chronic toxicity</td><td>ISO10993-11:2006</td></tr>
<tr><td>Pyrogenicity</td><td>ISO10993-11:2006</td></tr>
<tr><td>Exhaustive Extraction</td><td>ISO10993-18: 2005</td></tr>
<tr><td>Extract Analysis</td><td>ISO10993-18:2005</td></tr>
<tr><td>Particulate matter</td><td>EN45502-1:2015</td></tr>
</table></td><td></td></tr>
<tr><td>Sterility</td><td>The implant is provided sterile and is implanted in a surgical setting like the predicate. The sound processor is provided non-sterile.</td><td>Same</td></tr>
<tr><td>Clinical Performance</td><td colspan="2">Clinical performance data was gathered through a simulation study that allowed audiological testing of the Osia 2 Systems and Osia Systems without having to surgically implant the OSI200 Implant and OSI100 Implant, respectively. The clinical evaluation did not reveal significant differences in hearing performance between either system in regard to adaptive speech recognition (p-value > 0.05). The stimulation study did not raise new issues of safety nor effectiveness for the Osia 2 System and supported substantial equivalence between the Osia 2 System and the predicate Osia System.</td></tr>
</table>

As required by the Special Controls identified for this device type, a summary of the clinical data is provided in the product labeling.

K. Conclusion

Despite the physical differences and additional features of the Osia 2 System when compared to the predicate Osia System, they have substantially equivalent function, technology and intended use.

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