August 18, 2023

Cochlear
Denis DiMartino
Senior Regulatory Affairs Specialist
10350 Park Meadows Drive
Lone Tree, Colorado 80124

Re: K231204
Trade/Device Name: Cochlear™ Osia® System; Cochlear™ Osia® OSI300 Implant; Cochlear™ Magnet Cassette; Cochlear™ Non-Magnetic Cassette; Cochlear™ Osia® 2(I) Sound Processor; Cochlear™ Osia® Fitting Software 2; 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: July 19, 2023
Received: July 19, 2023

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 (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,

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
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)*
K231204

Device Name
Cochlear™ Osia® 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 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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**510(k) Summary**

## A. Submitter Information

| | |
|---|---|
| Submitted by: | Cochlear Americas<br>10350 Park Meadows Drive<br>Lone Tree, CO 80124 |
| On behalf of the manufacturer: | Cochlear Ltd – Macquarie<br>1 University Avenue<br>Macquarie University, NSW 2109<br>Australia<br>(Establishment Number 3009092818) |
| Contact: | Denis DiMartino<br>Senior Regulatory Affairs Specialist<br>Cochlear Americas<br>C: 508-304-4356<br>E: ddimartino@cochlear.com |

## B. Date Prepared

**19-July-2023**

## C. Device Name and Classification

| | |
|---|---|
| Device Names: | Cochlear™ Osia® OSI300 Implant<br>Cochlear™ Magnet Cassette<br>Cochlear™ Non-Magnetic Cassette<br>Cochlear™ Osia® 2(I) Sound Processor<br>Cochlear™ Osia® Fitting Software 2<br>Cochlear™ Osia® Smart App |
| Trade/Proprietary Name: | Cochlear™ Osia® System |
| Common/Usual Name: | Osia System |
| Classification Name: | Active implantable bone conduction hearing system<br>21 CFR 874.3340, Class II |
| Classification Panel: | Ear, Nose, and Throat |
| Product Code: | PFO |

## D. Predicate Device

| | |
|---|---|
| Device Names: | Cochlear™ Osia® OSI200 Implant<br>Cochlear™ Osia® 2 Sound Processor<br>Cochlear™ Osia® Fitting Software 2<br>Cochlear™ MRI Kit |

| | |
|---|---|
| Trade/Proprietary Name: | Cochlear™ Osia® 2 System |
| Common/Usual Name: | Osia System |
| Classification Name: | Active implantable bone conduction hearing system<br>21 CFR 874.3340, Class II |
| Classification Panel: | Ear, Nose, and Throat |
| Product Code: | PFO |
| 510(k): | K220922 |

**E. Purpose of Submission**

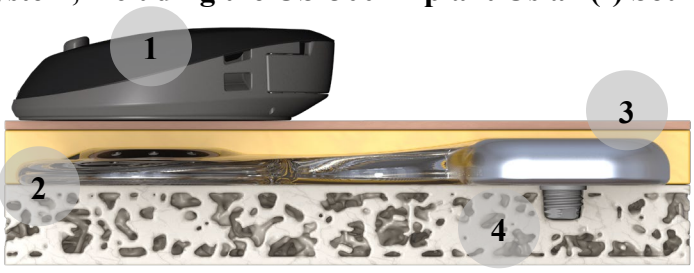
This Traditional 510(k) seeks clearance for an updated Osia System, which includes a new OSI300 Implant, a new Cochlear Magnet Cassette and Non-Magnetic Cassette, and a new Osia 2(I) Sound Processor. Additionally, the updated Osia System includes modifications to existing components (Osia 2 Sound Processor, Osia Fitting Software 2, and Osia Smart App). The previous Osia System, Osia 2 System (predicate), was cleared under K220922 on July 27th, 2022.

**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 (OSI300) 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 OSI300 Implant Osia 2(I) 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 updated Osia System introduces:

- The OSI300 Implant with a rotatable magnet,
- The Cochlear Magnet and Non-Magnetic Cassettes for the OSI300 implant
- The Osia 2(I) Sound Processor for compatibility with the OSI300 implant,
- New dedicated 'Imaging' magnets (denoted as (I) magnets) for the Osia 2(I) Sound Processor,
- New magnet tool for the (I) magnets,
- Updates to the cleared Osia Fitting Software 2 to support the OSI300 implant along with other improvements, described further below, and
- Minor updates to the Osia Smart App.

**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 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.

## 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.

Both the updated Osia System and the predicate Osia 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 System, which includes a new OSI300 Implant and Osia 2(I) Sound Processor, and modifications to the Osia 2 Sound Processor, Osia Fitting Software 2, and Osia Smart App, has the same intended use and the same fundamental operating principles as the predicate Osia 2 System. The updated Osia System introduces the OSI300 Implant and Osia 2(I) Sound Processor to allow for the patient to be examined by an MRI at 1.5T and 3T without having the implant magnet removed or requiring use of an MRI kit.

**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 2 System (Predicate, K220922) | Osia System (Subject) |
|---|---|---|
| **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. | Same |
| **Indications** | The Osia System is intended for the following patients and indications:<br>• Patients 12 years of age or older.<br>• Patients who have a conductive or mixed hearing loss and still | Same |

| Technological Characteristic | Osia 2 System (Predicate, K220922) | Osia System (Subject) |
|---|---|---|
| | 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.<br>• 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.<br>• 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).<br>• 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.<br>• 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 | Same |

| Technological Characteristic | Osia 2 System (Predicate, K220922) | Osia System (Subject) |
|---|---|---|
| | 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. | |
| **System Compatibility** | The Osia 2 System includes an implant, sound processor, surgical tools and accessories, software, programming cable, and fitting software.<br><br>It is also capable of wireless connection to accessories and the fitting software. | Same |
| **Implant** | OSI200 Implant | Different. Introducing the OSI300 implant, which is designed with a rotatable magnet to allow the patient to be examined by an MRI at 1.5T and at 3T without having the implant magnet removed or requiring use of an MRI kit |
| **Osseointegrated Implant** | BI300 (K100360) | Same |
| **Biocompatibility of Implant** | Biocompatibility of the Osia System has been evaluated and tested. All tests were passed and confirm that the Osia System is biocompatible.<br><br>The OSI200 Implant was 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 | Same - The changes to the implant do not impact the product characteristics that were verified with the predicate. There is no change to the surfaces and materials of the device that contacts the body. Verification is leveraged from the previous OSI200 Implant device cleared by the FDA under |

| Technological Characteristic | Osia 2 System (Predicate, K220922) | Osia System (Subject) |
|---|---|---|
| | risk management process" (2016), for a permanent (>30 days) implant device contacting tissue and bone and can be considered safe for use. | K191921 with additional testing performed for the coil magnet assembly. |
| **Sterilization of Implant** | Each OSI200 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 for the OSI300 Implant. |
| **Shelf Life and Packaging-Implant** | Shelf-life of the OSI200 Implant is 2.5 years.<br><br>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 for the OSI300 Implant. |
| **Implant Reliability Testing and Performance Data** | The verification tests for performance and reliability of the OSI200 Implant include those related to:<br>Acoustic Output, Link Integrity, Fixation Screw, Static Load, Coil Impact, Cyclic Load, Static Load, Lifetime Testing, Hermeticity, Coil Robustness, Fluid Ingress, Particulate Matter Testing, Maximum Surface Temperature, and Environmental Conditioning. | Similar, some test results previously cleared were not re-run and new tests for the OSI300 implant were conducted. |
| **MRI Compatibility** | The Osia System is MR Conditional. | The Osia System remains MR Conditional; however, MR Conditions have changed:<br><br>The OSI300 implant is designed to allow the patient to be examined |

| Technological Characteristic | Osia 2 System (Predicate, K220922) | Osia System (Subject) |
|---|---|---|
| | | by an MRI at 1.5T and at 3T without having the implant magnet removed or requiring use of an MRI kit. |
| **Sound Processor** | Osia 2 Sound Processor | Similar.<br><br>The Osia 2(I) sound processor is nearly identical to the Osia 2 sound processor, except that the RF link circuitry is tuned in production with a 4(I) magnet to attain an optimum RF link performance for the strongest 4(I) magnet, which is to be used for the largest skin flap thickness range. |
| **Sound Processor Function** | The Osia 2 System requires the use of an externally worn sound processor that is worn on the head behind the ear.<br><br>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. | Same, with new OSI300 Implant. |
| **Sound Processor Magnet** | The Osia 2 Sound Processor uses standard axial magnets (M1, M2, M3, M4) that are compatible with the OSI100 and OSI200 implant magnets. | Different, the updated magnets for the Osia 2(I) sound processor allow for compatibility with the magnet introduced in the OSI300 Implant. |
| **Sound Processor Firmware** | The Osia 2 Sound Processor chipset includes two distinct blocks: one block is based on the GN Hearing C4.5/Palpatine platform, and is responsible for receiving the | Similar, the firmware has been updated with new functionalities to support the OSI300 Implant. |

| Technological Characteristic | Osia 2 System (Predicate, K220922) | Osia System (Subject) |
|---|---|---|
| | 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. | |
| **Contact and Biocompatibility of Sound Processor** | The Osia 2 Sound Processor is an intact-skin contacting device for permanent use.<br><br>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 |
| **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. | Same, for the Osia 2(I) Sound Processor. |
| **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.<br><br>It is a stand-alone software. | Similar, new features are available in the Osia Fitting Software 2 to support the changes to the Osia 2(I) Sound Processor and OSI300 Implant. |
| **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.<br><br>Available for Android and iOS. | Similar. The Osia Smart App has been updated to support identification of the Osia 2(I) sound processor and OSI300 implant. |

Additional details on the new features and functionalities for the subject devices are provided below:

**OSI300 Implant**

- The OSI300 implant is designed with a rotatable magnet to allow the patient to be examined by an MRI at 1.5T and at 3T without having the implant magnet removed or requiring use of an MRI kit.
- The standard magnets used in the predicate implant devices are replaced by imaging magnets which have a different magnetization polarity. This change enables 1.5T and 3T MRI examinations with magnet in place, and without the need for a supporting bandage or splint. The Cochlear Magnet Cassette provides retention of the sound processor for the OSI300 implant, as the Cochlear Sterile Replacement Magnet does for the OSI200 implant. The Magnet Cassette on the OSI300 implant contains a magnet which can rotate when subjected to magnetic fields. It is intended to be used to replace the magnet of the hearing implant that has been removed to facilitate a medical procedure.
- The Non-Magnetic Cassette serves the same function for the OSI300 implant as the Cochlear Sterile Non-Magnetic Plug serves for the OSI200 implant. It is intended to be used temporarily in place of the magnet cassette of a hearing implant after the implant magnet cassette is removed.

**Osia 2(I) Sound Processor**

- The Osia 2(I) Sound Processor is developed from the Osia 2 Sound Processor with fine tuning of the radiofrequency (RF) link to optimize compatibility with the OSI300 implant
    - The hardware remains unmodified from the predicate device.
    - The firmware has been updated to allow the Sound Processor to detect the updated OSI300 implant
    - Relevant finetuning improvements have also been made to the Osia 2 Sound processor, and the new firmware version is used in both the Osia 2 Sound Processor and the Osia 2(I) Sound Processor.
- New Imaging Magnets (1(I), 2(I), 3(I), and 4(I)), with updated magnetization polarity compared to the standard magnets used for the Osia 2 Sound Processor, are introduced for retention of the Osia 2(I) Sound Processor to the magnet cassette of the OSI300 Implant.
- The Osia 2(I) Magnet Tool serves the same function as the Osia 2 Magnet tool, i.e., use for removal of the sound processor magnet from the sound processor base. It was updated for the changed magnetization polarity of the (I) magnets used for the Osia 2(I) sound processor.

**Osia Fitting Software 2**

- Updated to be able to identify Osia 2(I) Sound Processor and OSI300 Implant
- Updated Cochlear Baha Prescription to improve the sound quality and to reduce the sharpness of the sound

**Osia Smart App**

- Updated to support identification of Osia 2(I) Sound Processor and OSI300 Implant
- Minor user interface updates and bug fixing

## K. Performance Data

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

Verification activities for the new OSI300 Implant included performance testing re-executed to support:

- Functional verification
- Fixation Screw verification
- Safety and Reliability verification related to MRI Safety, Maximum Surface Temperature, Coil Tensile and Flexural Robustness, Magnet Retention, Fluid Ingress, Implant Impact, Coil Impact, Release of Particulate Matter, ESD
- Environmental Testing verification

The following verification testing performed on the cleared OSI200 Implant remains applicable to the new OSI300 Implant and were leveraged with justification from the predicate device.

- Safety and Reliability verification related to Diagnostic Ultrasound, Therapeutic Ionising Radiation, Implant High Power Electric Fields
- Surgical Implementation
- Sterilization
- Sterile Barrier
- Shelf-Life

Validation activities were completed for the OSI300 Implant and the Osia 2(I) Sound Processor to confirm that user needs were met. Previously completed validation and usability testing was leveraged where applicable for the updated Osia System.

Verification related to the OSI300 Implant was completed and concluded that the changes do not affect the safety and effectiveness of the device related to the:

- OSI300 Implant
- Sound Processor and its accessories
- Osia Fitting Software 2
- Osia Smart App

The results demonstrate the updated Osia System, including the new OSI300 Implant and Osia 2(I) sound processor, along with the modified Osia 2 Sound Processor, Osia Fitting Software 2, and Osia Smart App 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 System has been shown to be as safe and effective for its intended use as the predicate device.