July 3, 2019

Cochlear Americas
Laura Blair
Director Regulatory Affairs
13059 E. Peakview Avenue
Centennial, Colorado 80111

Re: K190589
Trade/Device Name: Cochlear Osia OSI100 Implant, Cochlear Osia Sound Processor, Osia Intraoperative Test Software, Osia Fitting Software, 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: June 6, 2019
Received: June 6, 2019

Dear Laura Blair:

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 Srinivas Nandkumar, Ph.D.
Assistant 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)*
K190589

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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1. 510(k) Summary

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:	Laura Blair Director, Regulatory Affairs Cochlear Americas lblair@cochlear.com (303) 264- 2752 (o) (303) 524-6825 (f)

B. Date Prepared 7/2/2019

C. Device Name and Classification

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

Trade/Proprietary Name:	Bonebridge™ System
Common/Usual Name:	Bonebridge System
Classification Name:	Active implantable bone conduction hearing system 21 CFR 874.3340, Class II
Classification Panel	Ear, Nose, and Throat
Product Code:	PFO

E. Purpose of Submission

This Traditional 510(k) seeks clearance for an active implantable bone conduction hearing system, known as the Cochlear™ Osia™ System. The Osia 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 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 System is made up of several components. The Osia Implant (OSI100) consists of a receiver/stimulator and an actuator (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.

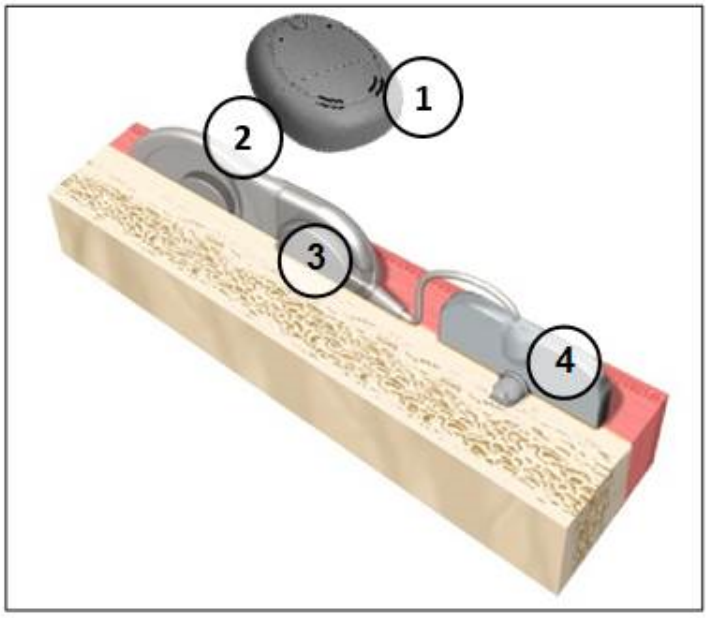

Figure 1: Overview of the Osia System, including the Osia Sound Processor

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.
3. The implant receiver-stimulator converts the digital information into an electric analogue signal.
4. This electric signal is converted to vibrations by the implant piezoelectric actuator.

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 System uses bone conduction to transmit sounds to the cochlea (inner ear). Cochlear 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 recommend that an individual have experience with appropriately fitted air conduction or bone conduction hearing aids.

I. Technological Characteristics

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 Osia System and the predicate 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.

The implant coil, magnet, case and lead assembly reuse the Freedom Cochlear Implant (CI24RE) platform (P970051/S028). This platform has been used in Cochlear's implantable systems for over ten years. The implant receiver-stimulator contains dedicated electronics whose power is supplied by the batteries in the external sound processor. The actuator is connected to the implant receiver-stimulator via a standard Cochlear lead, which contains a bundle of conductors grouped into two conductive paths. Just like the predicate device, an electromagnetic inductive link (also known as radio-frequency link) between the external sound processor coil and the implant coil allows sound data and power to be transmitted to the implant. A magnet located at the center of the implant coil allows the coil of the external sound processor to be placed in the correct position, over the receiver-stimulator coil, so that the inductive link is operational.

The actuator for the OSI100 Implant is a piezoelectric transducer which converts the signal into corresponding vibrations. The actuator design concept is conceived of a piezo bender connected to two identical tungsten moving masses. When the piezo is electrically driven by the stimulator electronics, a vibration is generated at the central fixation clamp, the location where the actuator is fixed to the bone by the Baha® BI300 Implant (K100360). The fixation system consists of the BI300 Bone Implant and the fixation screw to fix the piezoelectric actuator to the BI300 Bone Implant. The Osia Implant is attached via the osseointegrated BI300 Implant and the transducer of the predicate device is attached via the osseointegrated cortical screws. Although the method of attachment is not the same, both attachments (screw and implant) are made of titanium and are attached and dependent upon osseointegration. Both devices have an implanted transducer. The energy used and delivered by the Osia System is the same as the predicate device.

Both the Osia Sound Processor and the audio processor from the predicate device 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. Neither the Osia Sound Processor nor the Audio Processor of the predicate device contain software or are sterile.
Both the Osia System and the predicate have dedicated fitting software. Although the software platforms are different, both software platforms have a minor level of concern and are used for the same purpose.

Like the predicate device, the Osia Implant is provided sterile and is implanted in a surgical setting. Following programming of the sound processor, both the Osia System and the predicate system are used by the recipient in their daily life.

The Osia System has the same intended use, the same functional characteristics, the same fundamental operating principles, and is made of biocompatible materials like the predicate device. The Osia System can accommodate greater degrees of hearing loss (45 versus 55 dB). Force output measurements made at the same frequencies are higher for the Osia System, enabling the expanded fitting range of the Osia Sound Processor versus the predicate.

J. Materials

Like the predicate device, the Osia Implant is implanted in the mastoid bone and is a device in permanent tissue/bone contact. The Osia Sound Processor is classified as an intact-skin contacting device for permanent use.

Both the Osia Implant and Osia Sound Processor is made of medical grade plastics and metals that have been shown to be biocompatible and safe for human use. The Osia Implant is attached via the osseointegrated BI300 Implant and the transducer of the predicate device is attached via the osseointegrated cortical screws. Although the method of attachment is not the same, both attachments (screw and implant) are made of titanium and are attached and dependent upon osseointegration. Direct contact materials in the OSI100 Implant include, titanium, silicone, and platinum. Materials from the BCI 601 predicate device that are in contact with the body are silicone, titanium and polypropylene. Both the Osia System and the predicate device had biocompatibility testing completed in accordance with ISO 10993-1:2009.

K. Performance Data

Testing of the Osia System included testing to confirm patient safety, product usability and reliability, interoperability, and electromagnetic compatibility. Patient safety testing included biocompatibility testing as well as basic medical electrical safety testing. Usability was demonstrated through simulated use testing in a variety of use cases. Reliability testing was conducted through exposure of the device to mechanical stresses, and environmental extremes, and simulated long-term use followed by functional testing. Simulated testing has demonstrated that the lifetime of the OSI100 actuator is a minimum of six years. Interoperability testing was performed, including functional testing with existing Baha fixation systems, as well as the ability to perform a prescribed fitting through the Osia Fitting Software. Electromagnetic compatibility testing established that the device did not emit excessive amounts of electromagnetic energy, and that the device operated as intended in the presence of interference sources. Coexistence testing was performed, with the device paired and in a streaming configuration while exposed to various sources of in-band interference. The results of the testing indicate that the Osia System is substantially equivalent to the predicate device.

Clinical performance data was gathered in a multi-center trial. The investigation was an open, two-armed prospective clinical investigation that had one site in the United States. The study was not blinded. The investigation had a primary analysis endpoint at 3 months with an additional 9 months of follow up. The primary safety analysis was at 6 months. When compared to the pre-implant condition, data gathered with the Osia Device showed significant improvements in audiometric thresholds, speech in noise, and speech in quiet. Patient reported outcomes also demonstrated significant benefits. Although some test measures varied, based on the clinical data gathered with the Osia System, performance improvements are expected to be similar to the predicate device.

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

L. Conclusion

Despite the physical and material differences of the Osia System and the predicate device, the Osia System and the predicate have substantially equivalent function and technology, and

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