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

August 24, 2023

Re: K231604
Trade/Device Name: Instrument Case
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: July 27, 2023
Received: July 27, 2023

Dear Whitney Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.08.24 11:39:02 -04'00'

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K231604

Device Name
Instrument Case

Indications for Use *(Describe)*
The Instrument Case is intended for staff involved in reprocessing of reusable instruments, and for surgical teams.

The product shall only be used:

- in a controlled surgical environment under sterile conditions such as a hospital,
- in reprocessing environment at sterilization departments or reprocessing centers,
- and for transport of surgical instruments.

Sterilization parameters:
In US: Pre-Vacuum Steam at 132 °C (270 °F) for 4 min with a 20 minutes dry time
Outside US: See the Reprocessing Guide available in your country

The worse-case validated load for the Instrument Case, including instruments, is 1700 g.

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.

510(k) Summary

A. Submitter Information

Submitted by:	Cochlear Americas 10350 Park Meadows Drive Lone Tree, CO 80124
On behalf of the manufacturer:	Cochlear Bone Anchored Solutions AB Konstruktionsvägen 14, SE-435 33 Mölnlycke Sweden (Establishment Number 9616024)
Contact:	Whitney Alexander Regulatory Affairs Specialist II Cochlear Americas C: 719-337-8620 E: walexander@cochlear.com

B. Date Prepared **21-August-2023**

C. Device Name and Classification

Device Names:	Instrument Case
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories 21 CFR 880.6850, Class II
Classification Panel:	Orthopedic
Product Code:	KCT

D. Predicate Device

Device Names:	Instrument Case
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories 21 CFR 880.6850, Class II
Classification Panel:	Orthopedic
Product Code:	KCT
510(k):	K223672

E. Purpose of Submission

This Special 510(k) seeks clearance for an updated Instrument Case that is intended to hold reusable instruments used during surgical procedures for Osia® and Baha® bone conduction implants. Outside of surgery, the Instrument Case is designed to hold the reusable instruments during the sterilization process and for transportation of the instruments.

F. Device Description

The Instrument case, **Figure 1**, is a reusable sterilization container intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization. The specific use for the Instrument case is to hold reusable instruments during transport, the sterilization process, and during surgery.

The Instrument case consists of tray and lid made of stainless steel with a small box included, which is a component tray. The grommets, strips and holders that keep the instruments in place are made of silicone or stainless steel, and the latches in the lid are made of a Thermoplastic resin, Santoprene. The packaging materials are made of polyethylene and polyolefin.

Figure 1: Instrument Case

G. Intended Use

The Instrument Case is a medical device accessory intended to hold reusable surgical instruments during transportation, sterilization process and during surgery.

H. Indications for Use

The Instrument Case is intended for staff involved in reprocessing of reusable instruments, and for
surgical teams.

The product shall only be used:

- in a controlled surgical environment under sterile conditions such as a hospital,
- in reprocessing environment at sterilization departments or reprocessing centers,
- and for transport of surgical instruments.

Sterilization parameters:
In US: Pre-Vacuum Steam at 132 °C (270 °F) for 4 min with a 20 minutes dry time
Outside US: See the Reprocessing Guide available in your country

The worse-case validated load for the Instrument Case, including instruments, is 1700 g.

I. Technological Characteristics and Comparison to Predicate

Table 1 summarizes a comparison of the technological characteristics of the currently available Instrument Case (predicate device) with the updated Instrument Case (subject device).

Table 1: Technological Characteristics Comparison

Feature	Instrument Case (Subject Device)	Instrument Case (Predicate Device, K223672)	Comparison Notes
Manufacturer	Cochlear	Cochlear	Same
Class	II	II	Same
Product Code	KCT	KCT	Same
Intended Use	The Instrument Case is a medical device accessory intended to hold reusable surgical instruments during transportation, sterilization process and during surgery.	The Instrument Case is a medical device accessory intended to hold reusable surgical instruments during transportation, sterilization process and during surgery.	Same
Indications for Use	The Instrument Case is intended for staff involved in reprocessing of reusable instruments, and for surgical teams. The product shall only be used:	The Instrument Case is intended for staff involved in reprocessing of reusable instruments, and for surgical teams. The product shall only be used:	Similar. Minor sentence added to support global distribution of the device. The difference does not affect the safety and performance of

Feature	Instrument Case (Subject Device)	Instrument Case (Predicate Device, K223672)	Comparison Notes
	• in a controlled surgical environment under sterile conditions such as a hospital, • in reprocessing environment at sterilization departments or reprocessing centers, • and for transport of surgical instruments. Sterilization parameters: In US: Pre-Vacuum Steam at 132 °C (270 °F) for 4 min with a 20 minutes dry time Outside US: See the Reprocessing Guide available in your country The worst-case validated load for the Instrument Case, including instruments, is 1700 g.	• in a controlled surgical environment under sterile conditions such as a hospital, • in reprocessing environment at sterilization departments or reprocessing centers, • and for transport of surgical instruments. Sterilization parameters: Pre-Vacuum Steam at 132 °C (270 °F) for 4 min with a 20 minutes dry time The worst-case validated load for the Instrument Case, including instruments, is 1700 g.	the subject device.
General Design	Stainless steel instrument tray with a stainless steel locking lid and removable stainless steel component tray. Silicone instrument holders.	Stainless steel instrument tray with a stainless steel locking lid and removable stainless steel component tray. Silicone instrument holders.	Same, the subject device only differs with a few additional device etchings.
Dimensions	Length x Width x Height, mm 265 x 160 x 42	Length x Width x Height, mm 265 x 160 x 42	Same
Materials	Base Tray – Stainless steel Lid – Stainless steel Case tray – Stainless steel Tooling Support – Silicone	Base Tray – Stainless steel Lid – Stainless steel Case tray – Stainless steel	Same

Feature	Instrument Case (Subject Device)	Instrument Case (Predicate Device, K223672)	Comparison Notes
		Tooling Support – Silicone	
Sterility	Non-sterile	Non-sterile	Same
Sterilization Method	Dynamic air removal steam sterilization (prevacuum) to a Sterility Assurance Level (SAL) of $\leq 10^{-6}$	Dynamic air removal steam sterilization (prevacuum) to a Sterility Assurance Level (SAL) of $\leq 10^{-6}$	Same
Sterilization Parameters	132°C for 4 minutes with a 20 minutes drying time	132°C for 4 minutes with a 20 minutes drying time	Same
Reusable	Yes	Yes	Same
Useful Life	25 Cycles	25 Cycles	Same
Biocompatibility	Planning and testing have been carried out according to ISO 10993-1. The Instrument Case is biocompatible due to the testing with pass results.	Planning and testing have been carried out according to ISO 10993-1. The Instrument Case is biocompatible due to the testing with pass results.	Same
Perforated	Yes	Yes	Same
Sterile Barrier	FDA cleared sterilization pouch	FDA cleared sterilization pouch	Same
Maximum Load for Sterilization	1700g	1700g	Same
Compatible Reusable Instruments	Cochlear's bone-anchored reusable instrument portfolio and Elos Pinol's C9866 Multi wrench and C10110 Square adapter for Multi wrench	Cochlear's bone-anchored reusable instrument portfolio	Similar – Additional instrumentation validated for sterilization within Cochlear's instrument case.

J. Performance Data

Bench testing was conducted to demonstrate substantial equivalence to the predicate device, the Instrument Case (K223672). The predicate device and the subject device are identical, except for additional etchings. Substantial equivalence to the predicate device was accomplished through non-clinical data related to sterilization validation. The results demonstrate the Instrument Case

is substantially equivalent to the predicate device. The changes do not affect the safety and performance of the Instrument Case.

Table 2 identifies the performance data for the subject device, and all of the testing yielded PASS results. For the sterilization validation, two instruments were added for sterility testing of the subject device, and for the remaining performance data, the test results of the predicate device remained valid for the subject device. The performance data shows that the subject device is as safe and effective as the predicate device.

Table 2: Summary of Performance Data

Test	Test Methodology	Test Description	Acceptance Criteria	Results	Comparison
Automated cleaning (with enzymatic detergent)	AAMI TIR12:2010 AAMI TIR30:2011	• 6 simulated use cycles • 5 accumulation cycles • 3 efficacy cycles Visual inspection for any residual test soil, residual protein and hemoglobin levels and cytotoxicity testing for presence of detergent residuals.	No visible soil should remain on the test articles. Protein level should be <6.4 µg / cm^2 for the test articles. Hemoglobin level should be <2.2 µg / cm^2 for the test articles. No cytotoxic potential.	PASS. All units met the acceptance criteria. Positive and negative controls performed as anticipated. The Instrument case did not have a cytotoxic potential.	Same. Test results of predicate device remain valid for subject device.
Automated cleaning (with alkaline detergent)	AAMI TIR12:2010 AAMI TIR30:2011	• 6 simulated use cycles (same simulated use as for the enzymatic detergent). • 5 accumulation cycles • 3 efficacy cycles Visual inspection for any residual test soil, residual	No visible soil should remain on the test articles. Protein level should be <6.4 µg / cm^2 for the test articles. Hemoglobin level should be <2.2 µg /	PASS. All units met the acceptance criteria. Positive and negative controls performed as anticipated. The Instrument case did not have a	Same. Test results of predicate device remain valid for subject device.

Test	Test Methodology	Test Description	Acceptance Criteria	Results	Comparison
		protein and hemoglobin levels and cytotoxicity testing for presence of detergent residuals.	cm^2 for the test articles. No cytotoxic potential.	cytotoxic potential.	
Steam Sterilization **132˚C for 4 min and 20 min dry time**	AAMI TIR12:2010 ANSI/AAMI ST79:2017 ISO 17664:2017 ISO 17665-1:2006 ISO 11737-2:2009	Devices were inoculated with at least 106 Geobacillus stearothermophilus spores, placed in the test item and sterilized in double 510(k) cleared wraps in a cold spot of the sterilizer. For Sterility Assurance Level (SAL) the steam sterilization procedure was repeated for 3 half-cycles. After incubation of the devices and controls for 7 days, SAL was evaluated, and growth was compared with positive controls. For dry time evaluation the steam sterilization was repeated for 3 full cycles and the test article, devices and sterilization wraps were	All positive controls for SAL testing must result in growth of the indicator organism and all negative controls must result in no growth. There should be no bacterial growth on the devices. There should be no visible moisture present on the test article, devices or sterilization wraps after the full cycle exposure.	PASS. Positive and negative controls performed as anticipated. All devices were sterile and a SAL of ≤10-6 was achieved. No moisture was observed on the test article, devices or sterilization wraps.	New testing performed. The same protocol was re-run for sterilization validation of the subject device with two new instruments (Elos Pinol's C9866 Multi wrench and C10110 Square adapter for Multi wrench). The results are the same as those for the predicate device.

Test	Test Methodology	Test Description	Acceptance Criteria	Results	Comparison
		visually inspected for moisture.			
Lifecycle testing **Visual inspection**	Internal Test Method	Validation of 25 cycles of reprocessing including manual pre- cleaning, automated cleaning with thermal disinfection and sterilization. Visual inspections after each cycle and pictures taken every 5 cycle or if any damage is observed.	No visual corrosion, damage, or impurities on the Instrument Case.	PASS. The visual inspection did not detect any damage. Pictures that were taken after every 5 cycles confirmed this and showed that the laser markings were fully readable after up to 25 cycles of reprocessing.	Same. Test results of predicate device remain valid for subject device.
Lifecycle testing **Biocompatibility**	ISO 10993-1:2018	Chemical characterization using GC-MS and ICP-MS	Any residuals hazards detected should be below levels of toxicological concern (Margin of safety; MOS>1)	PASS. The semi-volatile and inorganic substances that were detected and that were of toxicological concern had a MOS>1	Same. Test results of predicate device remain valid for subject device.
Biocompatibility	ISO 10993-5; 2009	Cytotoxicity	Non-Cytotoxic	PASS. The instrument case is not cytotoxic	Same. Test results of predicate device remain valid for subject device.

K. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the predicate device K223672.