March 21, 2023

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

Re: K223672
Trade/Device Name: Instrument Case P1340904
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: February 23, 2023
Received: February 23, 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,

Colin O'neill -S

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)*
K223672

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:
Pre-Vacuum Steam at 132 °C (270 °F) for 4 min with a 20 minutes dry time

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:	Denis DiMartino Senior Regulatory Specialist Cochlear Americas C: 508-304-4356 E: ddimartino@cochlear.com

B. Date Prepared **21-March-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:	Surgical Trays
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories 21 CFR 880.6850, Class II
Classification Panel:	Orthopedic
Product Code:	KCT
Primary Predicate:	K212281

E. Purpose of Submission

This Traditional 510(k) seeks clearance for an 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, 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. The device dimensions are 265 x 160 x 42 mm (length x width x height) and the worst case recommended load is 1700 g.

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

This product 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:
Pre-Vacuum Steam at 132 °C (270 °F) for 4 min with a 20 minutes dry time

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 Surgical Trays (predicate device) with the Instrument Case (subject device).

Table 1: Predicate Comparison

Feature	Instrument Case (Subject Device)	K212281 (Predicate device)	Comparison Notes
Manufacturer	Cochlear	Sirona Dental Systems GmbH	Different Manufacturers
Class	II	II	Same
Product Code	KCT	KCT	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: • 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.	The Surgical Trays are intended for organizing, sterilizing and storing of instruments. The Surgical Trays are not intended to maintain sterility and are to be used in conjunction with a legally marketed, validated sterilization pouch. Sterilization parameters: Pre-Vacuum Steam at 132 °C (270 °F) for 4 min with a 20 minutes dry time	Similar – While the wording is slightly different both devices are used for the same processes. The sterilization parameters are identical. The maximum load for sterilization is

Feature	Instrument Case (Subject Device)	K212281 (Predicate device)	Comparison Notes
	Sterilization parameters: Pre-Vacuum Steam at 132 °C (270 °F) for 4 min with a 20 minutes dry time The worse-case validated load for the Instrument Case, including instruments, is 1700 g.	The tested Surgical Tray represents the worst-case validated load of 513.7g.	different, based on the total weight of reusable instruments included in the sterilization case. The Instrument Case is as safe and effective as the predicate device.
General Design	Stainless steel instrument tray with a stainless steel locking lid and removable stainless steel component tray. Silicone instrument holders.	Plastic tray with locking lid. Co-molded silicone and silicone grommet supports	Tray is different, but instrument support (silicone) is the same
Dimensions	Length x Width x Height, mm 265 x 160 x 42	Length x Width x Height, inches 7.3 x 5.5 x 2.4 (185.4 x 139.7 x 61 mm)	Similar
Materials	Base Tray – Stainless steel Lid – Stainless steel Case tray – Stainless steel Tooling Support – Silicone	Base – Radel 5000 Lid – Radel 5000 Overlay – Radel 5000 Tooling support - Silicone	Tray material is different, but tooling support is the same
Sterility	Non-sterile	Non-sterile	Same
Sterilization Method	Dynamic air removal steam sterilization (prevacuum) to a Sterility Assurance Level (SAL) of $\leq 10^{-6}$	Moist heat (steam) and has been validated to SAL of 10^{-6}	Same
Sterilization Parameters	Pre vacuum, 132°C for 4 minutes with a 20 minutes drying time	Pre vacuum, At 132°C for 4 minutes with a 20 minutes dry time	Same
Reusable	Yes	Yes	Same
Useful Life	25 Cycles	200 Cycles	Different, based on

Feature	Instrument Case (Subject Device)	K212281 (Predicate device)	Comparison Notes
			product validation
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.	Biocompatibility evaluation assessment for the Surgical Tray was performed according to ISO 10993- 1:2018 The test results confirm that the Surgical Trays are biocompatible for their intended use.	Same
Perforated	Yes	Yes	Same
Sterile Barrier	FDA cleared sterilization pouch	FDA cleared sterilization pouch	Same
Maximum Load for Sterilization	1700g	513.7g	Different, based on total weight of reusable instruments included in the sterilization case.

J. Performance Data

Bench testing was conducted to demonstrate substantial equivalence to the predicate device, Surgical Trays. Substantial equivalence to the predicate device was accomplished through non-clinical data related to performance testing, biocompatibility testing, and reprocessing information. The results demonstrated the Instrument Case is substantially equivalent to the predicate device.

Table 2 identifies the performance tests that were conducted on the subject device. All of the testing yielded PASS results, as shown in the table below. For the sterilization validation, both the predicate and subject device utilized the ISO 17665 standard as the test methodology. For the remaining performance data, similar or the same test methodology were used to show that the subject device is as safe and effective as the predicate device as shown in the table below:

Table 2: Performance Data

Test	Test Methodology	Test Description	Acceptance Criteria	Results
Automated cleaning (with	AAMI TIR12:2010	6 simulated use cycles	No visible soil should remain	PASS: All units met the

Test	Test Methodology	Test Description	Acceptance Criteria	Results
enzymatic detergent)	AAMI TIR30:2011	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.	on the test articles. Protein level should be <6.4 µg/cm2 for the test articles. Hemoglobin level should be <2.2 µg/cm2 for the test articles. No cytotoxic potential.	acceptance criteria. Positive and negative controls performed as anticipated. The Instrument case did not have a cytotoxic potential.
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 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/cm2 for the test articles. Hemoglobin level should be <2.2 µg/cm2 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.
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	Devices were inoculated with at least 106 Geobacillus stearothermophilus spores, placed in the test item and sterilized in double 510(k) approved wraps in a cold spot of the sterilizer.	All positive controls for SAL testing must result in growth of the indicator organism and all negative controls must result in no growth.	PASS: Positive and negative controls performed as anticipated. All devices were sterile and a SAL of ≤10-6 was achieved.

Test	Test Methodology	Test Description	Acceptance Criteria	Results
	ISO 11737-2:2009	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 visually inspected for moisture.	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.	No moisture was observed on the test article, devices or sterilization wraps.
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.
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	PASS: The semi-volatile and inorganic substances that were detected and that were of

Test	Test Methodology	Test Description	Acceptance Criteria	Results
			of safety; MOS>1)	toxicological concern had a MOS>1
Biocompatibility	ISO 10993-5; 2009	Cytotoxicity	Non-Cytotoxic	PASS: The instrument case is not cytotoxic

K. Conclusion

Based on the indications for use, technological characteristics, and substantial equivalence comparison to the predicate device, supported by non-clinical data, the Instrument Case has been shown to be as safe, as effective, and performs as well as or better than the legally marketed predicate device, K212281.