July 12, 2024

S.I.N. - Sistema de Implante Nacional S.A.
Denise Domiciano
Quality and Regulatory Manager
Rua Soldado Ocimar Guimarães da Silva,
421 São Paulo, São Paulo 03348-060
Brazil

Re: K241378
Trade/Device Name: S.I.N. Instrument Kits
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: May 15, 2024
Received: May 15, 2024

Dear Denise Domiciano:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2024.07.12 19:48:56 -04'00'

for: Christopher Dugard
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical

and Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241378

Device Name
S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Epikut PTG Surgical Kit

S.I.N. Instrument Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instrument Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instrument Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
Gravity displacement – Exposure at 121 °C for 30 minutes and 30 minutes dry time.
S.I.N. Instrument Kits are intended for sterilization of non-porous loads.
S.I.N. Instrument Kits are recommended not to be stacked during sterilization.
The combined weight of the Epikut PTG Surgical Kit and associated instruments is 632 grams.
The weight of the empty Epikut PTG Surgical Kit is 353 grams.

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
K241378

S.I.N. - Sistema de Implante Nacional S.A.
S.I.N. Instrument Kits

JUNE 25, 2024

ADMINISTRATIVE INFORMATION

Manufacturer Name	S.I.N. - Sistema de Implante Nacional S.A. Rua Soldado Ocimar Guimarães da Silva, 421 São Paulo, São Paulo 03348-060 BRAZIL Telephone +55 -11-21693000 ext 3236
Official Contact	Denise Domiciano, Quality and Regulatory Manager Email denise.domiciano@sinimplantsystem.com

Representative

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	S.I.N. Instrument Kits
Common Name	Instrument sterilization trays
Regulation Number	21 CFR 880.6850
Regulation Name	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Regulatory Class	Class II
Product Code	KCT
Classification Panel	General Hospital
Reviewing Office	Office of Surgical and Infection Control Devices (OHT4)
Reviewing Division	Division of Infection Control and Plastic Surgery Devices (DHT4B)

PREDICATE DEVICE INFORMATION

Primary predicate device is:
K201688, S.I.N. Instrument Kits, S.I.N. – Sistema de Implante Nacional S.A. Reference device:
K212404, S.I.N. Instrument Kits, S.I.N. – Sistema de Implante Nacional S.A.

SUBJECT DEVICE INDICATION FOR USE STATEMENT

Indications for Use for Epikut PTG Surgical Kit

S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider.
S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
Gravity displacement - Exposure at 121°C°C for 30 minutes and 30 minutes dry time.
S.I.N. Instruments Kits are intended for sterilization of non-porous loads.
S.I.N. Instruments Kits are recommended not to be stacked during sterilization.
The combined weight of the Epikut PTG Surgical Kit and the associated instruments is 632 grams.
The weight of the empty Epikut PTG Surgical Kit is 353 grams.

SUBJECT DEVICE DESCRIPTION

The subject device is a reusable rigid container, comprising a base (bottom), a removable inner tray, and a lid (cover). The subject device tray is to be used to organize and protect the instruments that are sterilized by the healthcare provider. The base, inner tray, and lid components are designed to be integrated into a single unit which contains and protects the interior components during sterilization. The tray is perforated to allow for penetration of the sterilant, is to be used with moist heat (steam) and requires the use of an FDA cleared wrap to maintain sterility. The subject device components are manufactured from injection molded polysulfone (PSU), and holders of various geometries to position instruments in the kits are manufactured from silicone.

TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE

The comparison of the Indications for Use Statements and technological characteristics for the subject device, the predicate device, and the reference device are provided at the end of this summary on pages 5-8.

The subject device is provided in one (1) size and one (1) configuration; the primary predicate device K201688 is provided in 5 sizes and 14 configurations. The subject device and the predicate device have similar overall dimensions, enclose similar volumes, and have similar vent to volume ratios. Differences in the dimensions and vent to volume ratios between the subject device and the predicate device are mitigated by the sterilization validation performed.

SUMMARY OF NONCLINICAL TESTING

Provided below are the nonclinical test methodologies performed to demonstrate the subject device meets the acceptance criteria of the standard.

Summary of Nonclinical Testing Table

Test Methodology	Purpose	Acceptance Criteria	Results
Manual Cleaning Validation FDA Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (issued March 2015 *Referenced from K201688*	The purpose of this test is to validate that the cleaning instructions provided in the Instructions for Use appropriately clean the tray, and to ensure the sterilization cycle will be effective.	Protein assay Acceptance criterion: No color change = absence of protein residue Sensitivity = 1 µg protein residue Total organic carbon assay Acceptance criterion: results < limit of quantification = 0.1 ppm; Assay limit of detection = 0.015 ppm	Pass Pass
Bacterial Endotoxin Testing, USP <85> *Referenced from K201688*	The purpose of this test is to validate that the cleaning instructions provided in the Instructions for Use appropriately clean the tray, and to ensure the BET level meets FDA expectation (≤ 20 EU/device)	Acceptance criterion: Endotoxin results : ≤ 20 EU/device	Pass
Sterilization Validation including sterilant penetration and dry time validation ANSI/AAMI/ISO 17665-1 ANSI/AAMI/ISO 17665-2 *Referenced from K201688*	The purpose of this test is to validate that the sterilization instructions listed in the Instructions for Use appropriately sterilize the tray and contents.	Acceptance criterion: 3 consecutive half-cycles performed for each of 3 sizes of trays demonstrate complete inactivation of all biologic indicators. A minimum SAL of 10^{-6} is achieved if the Instructions for Use are followed	Pass
Dry time *Referenced from K201688*	The purpose of this test is to validate that the sterilization instructions listed in the Instructions for Use appropriately dry the wrapped tray for storage.	Acceptance criterion: Using pre-cycle and post-cycle weights, the weight gain after drying will be ≤ 3%	Pass
Life Cycle / Simulated Use-life Validation FDA Guidance Reprocessing Medical Devices in *Health Care Settings: Validation Methods and Labeling* (issued March 2015) *Referenced from K201688*	The purpose of this test is to validate the service life of the trays as stated in the Instructions for Use.	Acceptance criteria: Visual inspection, component dimensional fit verification, functional closure/latch verification for 250 use cycles	Pass
Biocompatibility of Subject Device Cytotoxicity testing ANSI/AAM.T/.ISO 10993-5 ANSI/AAM.T/ ISO 10993- 12 *Referenced from K201688 and K212404*	The purpose of this test is to evaluate the cytotoxicity potential of the test article using an in vitro cell culture assay.	Acceptance criterion: Non-cytotoxic if :≤ 50% of L-929 cells exposed to extract of device show rounding and lysis	Pass

In summary, the nonclinical testing provided for the subject device met the acceptance criteria for each standard and test methodology used to evaluate the subject device as shown in the table above.

No clinical data was included in this submission.

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the subject device in this 510(k) submission, K241378, S.I.N. Instrument Kit, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K201688.

Indications for Use Statements

	Indications for Use Statements
Subject Device – K241378 S.I.N. Instrument Kits S.I.N.- Sistema de Implante Nacional S.A.	
Epikut PTG Surgical Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Epikut PTG Surgical Kit and the associated instruments is 632grams. The weight of the empty Epikut PTG Surgical Kit is 353 grams.
Primary Predicate Device – K201688 S.I.N. Instrument Kits S.I.N. – Sistema de Implant Nacional S.A.	
Safe Drill Unitite Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Safe Drill Unitite Kit and the associated instruments is 304 grams. The weight of the empty Safe Drill Unitite Kit is 150 grams.
Safe Drill SW Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Safe Drill SW Kit and the associated instruments is 278 grams. The weight of the empty Safe Drill SW Kit is 138 grams.
Prosthetic Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Prosthetic Kit and the associated instruments is 332 grams. The weight of the empty Prosthetic Kit is 160 grams.
Rotatory Expanding Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Rotatory Expanding Kit and the associated instruments is 276 grams. The weight of the empty Rotatory Expanding Kit is 133 grams.
Bone Expander Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Bone Expander Kit and the associated instruments is 974 grams. The weight of the empty Bone Expander Kit is 367 grams.

Sinus Lift Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C °C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Sinus Lift Kit and the associated instruments is 808 grams. The weight of the empty Sinus Lift Kit is 370 grams.
Osteotome Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C °C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Osteotome Kit and the associated instruments is 957 grams. The weight of the empty Osteotome Kit is 350 grams.
Unitite Surgical Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C °C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Unitite Surgical Kit and the associated instruments is 1126 grams. The weight of the empty Unitite Surgical Kit is 515grams.
Strong SW Surgical Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C °C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Strong SW Surgical Kit and the associated instruments is 698 grams. The weight of the empty Strong SW Surgical Kit is 130 grams.
Tryon Surgical Kit KCHE 03	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C °C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Tryon Surgical Kit KCHE 03 and the associated instruments is 1127 grams. The weight of the empty Tryon Surgical Kit KCHE 03 is 520 grams.
Tryon Surgical Kit KCHE 04	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C °C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Tryon Surgical Kit KCHE 04 and the associated instruments is 1138 grams. The weight of the empty Tryon Surgical Kit KCHE 04 is 523 grams.
Unitite Surgical Guided Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C °C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Unitite Surgical Guided Kit and the associated instruments is 1434 grams. The weight of the empty Unitite Surgical Guided Kit is 650 grams.

Strong SW Surgical Guided Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C °C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Strong SW Surgical Guided Kit and the associated instruments is 1399 grams. The weight of the empty Strong SW Surgical Guided Kit is 647 grams.
Zygomatic Surgical Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kitsrequire the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C °C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Zygomatic Surgical Kit and the associated instruments is 1150 grams. The weight of the empty Zygomatic Surgical Kit is 464 grams.
Reference Device – K2I2404 S.I.N. Instrument Kits S.I.N. – Sistema de Implante Nacional S.A.	
Safe Drill Epikut Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kitsrequire the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C °C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Safe Drill Epikut Kit and the associated instruments is 154 grams. The weight of the empty Safe Drill Epikut Kit is 138 grams.
Unitite Surgical Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kitsrequire the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C °C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Unitite Surgical Kit and the associated instruments is 620 grams. The weight of the empty Unitite Surgical Kit is 520 grams.
Epikut Surgical Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kitsrequire the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C °C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Epikut Surgical Kit and the associated instruments is 605 grams. The weight of the empty Epikut Surgical Kit is 520 grams.
Epikut Surgical Guided Kit	S.I.N. Instruments Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instruments Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instruments Kitsrequire the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Gravity displacement – Exposure at 121°C °C for 30 minutes and 30 minutes dry time. S.I.N. Instruments Kits are intended for sterilization of non-porous loads. S.I.N. Instruments Kits are recommended not to be stacked during sterilization. The combined weight of the Epikut Surgical Guided Kit and the associated instruments is 808 grams. The weight of the empty Epikut Surgical Guided Kit is 650 grams.

Technological Characteristics

Attribute	Subject Device			Primary Predicate Device	Reference Device		Comparison
	K241378 S.I.N. Instrument Kits S.I.N. - Sistema de Implante Nacional S.A.			K206188 S.I.N. Instrument Kits S.I.N. - Sistema de Implante Nacional S.A.	K212404 S.I.N. Instrument Kits S.I.N.. - Sistema de Implante Nacional S.A.		
Product Code	KCT			KCT			Same
Design	Rigid polymer base, lid, and removable inner tray			Rigid polymer base, lid, and removable inner tray			Same
Materials	Polysulfone (base, tray, lid); Medical grade silicone (grommets)			Polysulfone (base, tray, lid); Medical grade silicone (grommets)			Same
Materials Compatible with Sterilization Method	Yes			Yes			Same
Perforated	Yes; allows moist heat (steam) penetration to achieve sterilization			Yes, allows moist heat (steam) penetration to achieve sterilization			Same
Reusable	Yes			Yes			Same
Number of Sizes/Configurations	1 size, 1 configuration			K201688 - 5 sizes, 14 configurations			Similar
Dimensions and Vent to Volume Ratio	Subject Device Tray	Length x Width x Height, mm	Vent to Volume Ratio	**Trays in K201688**	Length x Width x Height, mm	Vent to Volume Ratio	Similar
	COSEP 01, Epikut PTG Surgical Tray	215 x 100 x 35.5	0.0087 cm^2 / cm^3	COUSD 02, Safe Drill Unitite Tray	113.7 x 75.7 x 29.5	0.0089cm2 / cm3	
				COWSD 02, Safe Drill SW Tray	113.7 x 75.7 x 29.5	0.0089cm2 / cm3	
				COTMEC, Prosthetic Tray	113.7 x 75.7 x 29.5	0.0089cm2 / cm3	
				COER, Rotatory Expanding Tray	113.7 x 75.7 x 29.5	0.0089cm2 / cm3	
				COEXP, Bone Expander Tray	113.7 x 75.7 x 29.5	0.0100cm2 / cm3	
				COLEV, Sinus Lift Tray	215 x 100 x 33.5	0.0100 cm2 / cm3	
				COOST, Osteotome Tray	113.7 x 75.7 x 29.5	0.0100cm2 / cm3	
				COSU 03, Unitite Surgical Tray	165 x 190 x 55	0.0086cm2 / cm3	
				COSW 02, Strong SW Surgical Tray	165 x 190 x 55	0.0086cm2 / cm3	
				COHE 03, Tryon Surgical Tray KCHE 03	165 x 190 x 55	0.0086cm2 / cm3	
				COHE 04, Tryon Surgical Tray KCHE 04	165 x 190 x 55	0.0086cm2 / cm3	
				COSUG 02, Unitite Surgical Guided Tray	142 x 206 x 72	0.0083 cm2 / cm3	
				COSWG 02, Strong SW Surgical Guided Tray	165 x 190 x 55	0.0083 cm2 / cm3	
				COKZ, Zygomatic Surgical Tray	113.7 x 75.7 x 29.5	0.0131 cm2 / cm3	
				Trays in K2I2404			
				COESD 02, Safe Drill Epikut Tray	118 x 78.25 x 29.2	0.0083 cm^2 / cm^3	
				COSU 04, Unitite Surgical Tray	165x190 x 55	0.0086cm^2 / cm^3	
				COSE 01, Epikut Surgical Tray	165 x190 x 55	0.0086cm^2 / cm^3	
				COSEG 01I, Epikut Surgical Guided Tray	142x 206 x 72	0.0083 cm^2 / cm^3	
Reusable	Reusable up to 250 cycles			Reusable up to 250 cycles			Same
Use-life Testing	Disassembled, cleaned, assembled, sterilized Visual inspection. Component dimensional fit verification Functional closure (lid-base latch) verification			Disassembled, cleaned, assembled, sterilized Visual inspection Component dimensional fit verification Functional closure (lid-base latch) verification			Same
Sterilization Method							
Sterilant	Moist heat (steam)			Moist heat (steam)			Same
Cycles	Gravity displacement – Exposure at 121°C °C for 30 minutes and 30 minutes dry time.			Gravity displacement - Exposure at 121°C °C for 30 minutes and 30 minutes dry time			Same
Sterile Barrier	Sterilization wrap, FDA cleared for indicated method and cycle			Sterilization wrap, FDA cleared for indicated method and cycle			Same