November 2, 2021

S.I.N. - Sistema de Implante Nacional S.A.
% Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K212404
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: August 2, 2021
Received: August 2, 2021

Dear Kevin Thomas:

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 and Part 809); 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,

Clarence W. Murray, III, PhD
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212404

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Safe Drill Epikut 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 Safe Drill Epikut Kit and the associated instruments is 154 grams.
The weight of the empty Safe Drill Epikut Kit is 138 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Paperwork Reduction Act (PRA) Staff
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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)*
K212404

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Unitite 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 Unitite Surgical Kit and the associated instruments is 620 grams.
The weight of the empty Unitite Surgical Kit is 520 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)

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See PRA Statement below.

510(k) Number *(if known)*
K212404

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Epikut 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 Surgical Kit and the associated instruments is 605 grams.
The weight of the empty Epikut Surgical Kit is 520 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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Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212404

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Epikut Surgical Guided 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 Surgical Guided Kit and the associated instruments is 808 grams.
The weight of the empty Epikut Surgical Guided Kit is 650 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.

510(k) Summary

K212404

S.I.N. – Sistema de Implante Nacional S.A.

S.I.N. Instrument Kits

October 21, 2021

ADMINISTRATIVE INFORMATION

Manufacturer Name	S.I.N. – Sistema de Implante Nacional S.A. Avenida Vereador Abel Ferreira, 1100 São Paulo, São Paulo 03340-000 Brazil Telephone +55-11-21693000 ext 3236
Official Contact	Denise Domiciano, Quality and Regulatory Manager
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Fax +1 858-792-1236 Email kthomas@paxmed.com flarson@paxmed.com

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
The primary predicate device is:
K201688, S.I.N. Instrument Kits, S.I.N. – Sistema de Implante Nacional S.A.

SUBJECT DEVICE INDICATIONS FOR USE STATEMENTS

Indications for Use for Safe Drill Epikut 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 Safe Drill Epikut Kit and the associated instruments is 154 grams.
The weight of the empty Safe Drill Epikut Kit is 138 grams.

Indications for Use for Unitite 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 Unitite Surgical Kit and the associated instruments is 620 grams.
The weight of the empty Unitite Surgical Kit is 520 grams.

Indications for Use for Epikut 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 Surgical Kit and the associated instruments is 605 grams.
The weight of the empty Epikut Surgical Kit is 520 grams.

Indications for Use for Epikut Surgical Guided 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 Surgical Guided Kit and the associated instruments is 808 grams.
The weight of the empty Epikut Surgical Guided Kit is 650 grams.

SUBJECT DEVICE DESCRIPTION

The subject device includes a total of 4 instrument trays. The subject device trays are reusable rigid containers, comprising a base (bottom), one or more removable inner trays, and a lid (cover). The subject device trays are 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 trays are perforated to allow for penetration of the sterilant, are to be used with moist heat (steam), and require 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 instrument in the kits are manufactured from silicone. The subject device includes a total of 3 sizes (same lid, base, and enclosed volume), and a total of 4 tray configurations.

TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE

The comparison of the technological characteristics and Indications for Use Statements for the subject devices and the predicate device are provided at the end of this summary on pages 6-8.

The subject device is provided in 3 sizes and 4 configurations; the 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 devices met 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/AAMI/ISO 10993-5 ANSI/AAMI/ISO 10993-12	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 these devices met the acceptance criteria for each standard and test methodology used to evaluate the devices as shown in the table above.

No clinical data were included in this submission.

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the subject device in 510(k) submission K212404, S.I.N. Instrument Kits, is as safe, as effective, and perform as well as or better than the legally marketed predicate device cleared under K201688.

Indications for Use Statements

	Indications for Use Statements
Subject Device K212404 S.I.N. Instrument Kits S.I.N. - Sistema de Implante Nacional S.A.	Indications for Use for Safe Drill Epikut 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 Safe Drill Epikut Kit and the associated instruments is 154 grams. The weight of the empty Safe Drill Epikut Kit is 138 grams. Indications for Use for Unitite 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 Unitite Surgical Kit and the associated instruments is 620 grams. The weight of the empty Unitite Surgical Kit is 520 grams. Indications for Use for Epikut 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 Surgical Kit and the associated instruments is 605 grams. The weight of the empty Epikut Surgical Kit is 520 grams. Indications for Use for Epikut Surgical Guided 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 Surgical Guided Kit and the associated instruments is 808 grams. The weight of the empty Epikut Surgical Guided Kit is 650 grams.
Predicate Device K201688 S.I.N. Instrument Kits S.I.N. - Sistema de Implante Nacional S.A.	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.
Safe Drill Unitite Kit	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	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	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	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	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.

	Indications for Use Statements
Sinus Lift Kit	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	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	The combined weight of the Unitite Surgical Kit and the associated instruments is 1126 grams. The weight of the empty Unitite Surgical Kit is 515 grams.
Strong SW Surgical Kit	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	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	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	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	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	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.

Technological Characteristics

Attribute	Subject Device			Primary Predicate Device			Comparison
	K212404 S.I.N. Instrument Kits S.I.N. - Sistema de Implante Nacional S.A.			K201688 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	3			5			Similar
Total Number of Configurations	4			14			Similar
Dimensions and Vent to Volume Ratio	Tray	Length x Width x Height, mm	Vent to Volume Ratio	Tray	Length x Width x Height, mm	Vent to Volume Ratio	Similar
	COESD 02, Safe Drill Epikut Tray	118.0 x 78.25 x 29.2	0.0083 cm^2 / cm^3	COUSD 02, Safe Drill Unitite Tray	113.7 x 75.7 x 29.5	0.0089 cm^2 / cm^3	
	COSU 04, Unitite Surgical Tray	165 x 190 x 55	0.0086 cm^2 / cm^3	COWSD 02, Safe Drill SW Tray	113.7 x 75.7 x 29.5	0.0089 cm^2 / cm^3	
	COSE 01, Epikut Surgical Tray	165 x 190 x 55	0.0086 cm^2 / cm^3	COTMEC, Prosthetic Tray	113.7 x 75.7 x 29.5	0.0089 cm^2 / cm^3	
	COSEG 01I, Epikut Surgical Guided Tray	142 x 206 x 72	0.0083 cm^2 / cm^3	COER, Rotatory Expanding Tray	113.7 x 75.7 x 29.5	0.0089 cm^2 / cm^3	
				COEXP, Bone Expander Tray	113.7 x 75.7 x 29.5	0.0100 cm^2 / cm^3	
				COLEV, Sinus Lift Tray	215 x 100 x 33.5	0.0100 cm^2 / cm^3	
				COOST, Osteotome Tray	113.7 x 75.7 x 29.5	0.0100 cm^2 / cm^3	
				COSU 03, Unitite Surgical Tray	165 x 190 x 55	0.0086 cm^2 / cm^3	
				COSW 02, Strong SW Surgical Tray	165 x 190 x 55	0.0086 cm^2 / cm^3	
				COHE 03, Tryon Surgical Tray KCHE 03	165 x 190 x 55	0.0086 cm^2 / cm^3	
				COHE 04, Tryon Surgical Tray KCHE 04	165 x 190 x 55	0.0086 cm^2 / cm^3	
				COSUG 02, Unitite Surgical Guided Tray	142 x 206 x 72	0.0083 cm^2 / cm^3	
				COSWG 02, Strong SW Surgical Guided Tray	165 x 190 x 55	0.0083 cm^2 / cm^3	
				COKZ, Zygomatic Surgical Tray	113.7 x 75.7 x 29.5	0.0131 cm^2 / cm^3	
Reusable	Yes Reusable up to 250 cycles			Yes 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	Wrapped in a sterilizable wrap that is FDA cleared for the indicated cycle Gravity displacement 30 minute exposure at 121 °C (250 °F) 30 minute drying time			Gravity displacement			Same
Sterile Barrier	Sterilization wrap, FDA cleared for indicated method and cycle			Sterilization wrap, FDA cleared for indicated method and cycle			Same