October 21, 2020

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: K201688
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: September 15, 2020
Received: September 17, 2020

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); 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,

CAPT Elizabeth F. Claverie, MS
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)*

K201688

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Safe Drill Unitite 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 Unitite Kit and the associated instruments is 304 grams.
The weight of the empty Safe Drill Unitite Kit is 150 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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K201688

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Safe Drill SW 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 SW Kit and the associated instruments is 278 grams.
The weight of the empty Safe Drill SW 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)

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K201688

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Prosthetic 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 Prosthetic Kit and the associated instruments is 332 grams.
The weight of the empty Prosthetic Kit is 160 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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510(k) Number *(if known)*

K201688

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Rotatory Expanding 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 Rotatory Expanding Kit and the associated instruments is 276 grams.
The weight of the empty Rotatory Expanding Kit is 133 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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K201688

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Bone Expander 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 Bone Expander Kit and the associated instruments is 974 grams.
The weight of the empty Bone Expander Kit is 367 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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K201688

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Sinus Lift 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 Sinus Lift Kit and the associated instruments is 808 grams.
The weight of the empty Sinus Lift Kit is 370 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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510(k) Number *(if known)*

K201688

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Osteotome 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 Osteotome Kit and the associated instruments is 957 grams.
The weight of the empty Osteotome Kit is 350 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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510(k) Number *(if known)*

K201688

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 1126 grams.
The weight of the empty Unitite Surgical Kit is 515 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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510(k) Number *(if known)*

K201688

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Strong SW 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 Strong SW Surgical Kit and the associated instruments is 698 grams.
The weight of the empty Strong SW Surgical Kit is 130 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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510(k) Number *(if known)*

K201688

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Tryon Surgical Kit KCHE 03

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 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.

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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510(k) Number *(if known)*

K201688

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Tryon Surgical Kit KCHE 04

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 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.

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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K201688

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Unitite 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 Unitite Surgical Guided Kit and the associated instruments is 1434 grams.
The weight of the empty Unitite 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)

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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)*

K201688

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Strong SW 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 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.

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) Number *(if known)*

K201688

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Zygomatic 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 Zygomatic Surgical Kit and the associated instruments is 1150 grams.
The weight of the empty Zygomatic Surgical Kit is 464 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

K201688

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

S.I.N Instrument Kits

October 14, 2020

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 Division	Office of Surgical and Infection Control Devices (OHT4) Reviewing Division of Infection Control and Plastic Surgery Devices (DHT4B)

PREDICATE DEVICE INFORMATION

The primary predicate device is:

K182865, Neodent Instrument Kits, JJGC Indústria e Comércio de Materiais Dentários S.A.

SUBJECT DEVICE INDICATIONS FOR USE STATEMENTS

Indications for Use for Safe Drill Unitite 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 Unitite Kit and the associated instruments is 304 grams.
The weight of the empty Safe Drill Unitite Kit is 150 grams.

Indications for Use for Safe Drill SW 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 SW Kit and the associated instruments is 278 grams.
The weight of the empty Safe Drill SW Kit is 138 grams.

Indications for Use for Prosthetic 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 Prosthetic Kit and the associated instruments is 332 grams.
The weight of the empty Prosthetic Kit is 160 grams.

Indications for Use for Rotatory Expanding 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 Rotatory Expanding Kit and the associated instruments is 276 grams.
The weight of the empty Rotatory Expanding Kit is 133 grams.

Indications for Use for Bone Expander 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 Bone Expander Kit and the associated instruments is 974 grams.
The weight of the empty Bone Expander Kit is 367 grams.

Indications for Use for Sinus Lift 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 Sinus Lift Kit and the associated instruments is 808 grams.
The weight of the empty Sinus Lift Kit is 370 grams.

Indications for Use for Osteotome 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 Osteotome Kit and the associated instruments is 957 grams.
The weight of the empty Osteotome Kit is 350 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 1126 grams.
The weight of the empty Unitite Surgical Kit is 515 grams.

Indications for Use for Strong SW 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 Strong SW Surgical Kit and the associated instruments is 698 grams.
The weight of the empty Strong SW Surgical Kit is 130 grams.

Indications for Use for Tryon Surgical Kit KCHE 03
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 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.

Indications for Use for Tryon Surgical Kit KCHE 04
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 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.

Indications for Use for Unitite 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 Unitite Surgical Guided Kit and the associated instruments is 1434 grams.
The weight of the empty Unitite Surgical Guided Kit is 650 grams.

Indications for Use for Strong SW 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 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.

Indications for Use for Zygomatic 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 Zygomatic Surgical Kit and the associated instruments is 1150 grams.
The weight of the empty Zygomatic Surgical Kit is 464 grams.

SUBJECT DEVICE DESCRIPTION

The subject device includes a total of 14 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 5 sizes (same lid, base, and enclosed volume), and a total of 14 tray configurations.

TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE

The comparison of the Technological characteristics for the subject devices and the predicate device are provided at the end of the 510k summary on pages 7 – 10.

The subject device is provided in 5 sizes and 14 configurations; the predicate device K182865 is provided in 4 sizes and 4 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 non-clinical 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)	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>	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	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	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)	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 (by 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 devices are as safe, as effective, and performs as well as or better than the legally marketed predicate device.

Indications for Use Statements

	Indications for Use Statements
K201688 Subject Device S.I.N. Instrument Kits S.I.N. - Sistema de Implante Nacional S.A.	
Safe Drill Unitite 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 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. 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 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. 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 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. 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 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. 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 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. 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 Sinus Lift Kit and the associated instruments is 808 grams. The weight of the empty Sinus Lift Kit is 370 grams.

	Indications for Use Statements
Osteotome 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 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. 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 1126 grams. The weight of the empty Unitite Surgical Kit is 515 grams.
Strong SW 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 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. 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 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. 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 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. 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 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. 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 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.

	Indications for Use Statements
Zygomatic 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 Zygomatic Surgical Kit and the associated instruments is 1150 grams. The weight of the empty Zygomatic Surgical Kit is 464 grams.
Predicate Device	
K182865 Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	Indications for Use for GM/WS Surgical Kit Case: Neodent Instrument Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Neodent Instrument Kits are intended to allow sterilization of the enclosed medical devices. Neodent Instrument Kits require the use of FDA cleared wrap 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 one of the following cycles: Fractionated vacuum (pre-vacuum) – Exposure at 132 °C for 4 minutes, 20 minute dry time Gravity displacement – Exposure at 132 °C for 15 minutes, 20 minute dry time Neodent Instrument Kits are intended for sterilization of non-porous loads. The combined weight of the GM/WS Surgical Kit Case and the associated instruments is 674.5 g. The weight of the empty Kit Case is 507 grams. Neodent Instrument Kits are recommended not to be stacked during sterilization. Indications for Use for GM Prosthetic Kit Case: Neodent Instrument Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Neodent Instrument Kits are intended to allow sterilization of the enclosed medical devices. Neodent Instrument Kits require the use of FDA-cleared wrap 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 one of the following cycles: Fractionated vacuum (pre-vacuum) – Exposure at 132 °C for 4 minutes, 20-minute dry time Gravity displacement – Exposure at 132 °C for 15 minutes, 20-minute dry time. Neodent Instrument Kits are intended for sterilization of non-porous loads. The combined weight of the GM Prosthetic Kit Case and the associated instruments is 250.5 g. The weight of the empty Kit Case is 210 grams. Neodent Instrument Kits are recommended not to be stacked during sterilization. Indications for Use for GM Try-In Kit Case: Neodent Instrument Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Neodent Instrument Kits require the use of FDA-cleared wrap to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilizable wrap that is FDA-cleared for the indicated cycles, and moist heat (steam) sterilized using one of the following cycles: Fractionated vacuum (pre-vacuum) – Exposure at 132 °C for 4 minutes, 20-minute dry time. Gravity displacement – Exposure at 132 ºC for 15 minutes, 20-minute dry time. Neodent Instrument Kits are intended for sterilization of non-porous loads. The combined weight of the GM Try-In Kit Case and the associated instruments is 212.6 g. The weight of the empty Kit Case is 195 grams. Neodent Instrument Kits are recommended not to be stacked during sterilization. Indications for Use for GM Guided Surgery Kit Case: Neodent Instrument Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Neodent Instrument Kits are intended to allow sterilization of the enclosed medical devices. Neodent Instrument Kits require the use of FDA-cleared wrap 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 one of the following cycles: Fractionated vacuum (pre-vacuum) – Exposure at 132 °C for 4 minutes, 20-minute dry time Gravity displacement – Exposure at 132 °C for 15 minutes, 40-minute dry time. Neodent Instrument Kits are intended for sterilization of non-porous loads. The combined weight of the GM Guided Surgery Surgical Kit Case and the associated instruments is 728.4 g. The weight of the empty Kit Case is 567 grams. Neodent Instrument Kits are recommended not to be stacked during sterilization.

Technological Characteristics

Attribute	**Subject Device**			**Primary Predicate Device**			**Comparison**
	K201688 S.I.N. Instrument Kits S.I.N. - Sistema de Implante Nacional S.A.			K182865 Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários 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) Polyphenylsulfone (Radel R5000) (lid) Medical grade silicone (grommets) Titanium alloy (retention fixtures)			Similar
Materials Compatible with Sterilization Method described below.	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 Overall Tray Dimensions	5			4			Similar
Total Number of Configurations	14			4			Similar
Dimensions and Vent to Volume Ratio	Tray	Length x Width x Height, mm	Vent to Volume Ratio	Set	Length x Width x Height, mm	Vent to Volume Ratio	Similar
	COUSD 02, Safe Drill Unitite Tray	113.7 x 75.7 x 29.5	0.0089 cm^2 / cm^3	Set 110.287	264 x 163 x 54	0.0102 cm^2 / cm^3	
	COWSD 02, Safe Drill SW Tray	113.7 x 75.7 x 29.5	0.0089 cm^2 / cm^3	Set 110.294	195 x 90 x 54	0.0191 cm^2 / cm^3	
	COTMEC, Prosthetic Tray	113.7 x 75.7 x 29.5	0.0089 cm^2 / cm^3	Set 110.295	195 x 90 x 44	0.0247 cm^2 / cm^3	
	COER, Rotatory Expanding Tray	113.7 x 75.7 x 29.5	0.0089 cm^2 / cm^3	Set 110.296	264 x 163 x 58	0.0093 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			Yes			Same
Use Life Testing	Reusable up to 250 cycles Disassembled, cleaned, assembled, sterilized Visual inspection Component dimensional fit verification Functional closure (lid-base latch) verification			Reusable up to 100 cycles Assembled/disassembled, cleaned, sterilized Visual inspection Component dimensional fit verification Functional closure (lid-base latch) verification			Similar
Sterilization Method							
Sterilant	Moist heat (steam)			Moist heat (steam)			Same
Cycles	Gravity displacement 30 minute exposure at 121 °C (250 °F), with a 30 minute drying time; results in SAL of 10^{-6}			Gravity displacement 15 minute exposure at 132 °C (250 °F), with a 20 minute drying time			Same (SAL)
	(No other cycle validated)			Fractionated vacuum (pre-vacuum) 4 minute exposure at 132 °C (250 °F), with a 20 minute drying time			Not applicable
Sterile Barrier	Sterilization wrap, FDA cleared for indicated method and cycles			Sterilization wrap, FDA cleared for indicated method and cycles			Same