October 27, 2022

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

Re: K222514
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 19, 2022
Received: August 19, 2022

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,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222514

Device Name

S.I.N. Instrument Kits

Indications for Use *(Describe)*

Indications for Use for Epikut Long 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 Long Surgical Kit and the associated instruments is 422 grams.
The weight of the empty Epikut Long Surgical Kit is 310 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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510(k) Summary
K222514
S.I.N. – Sistema de Implante Nacional S.A.
S.I.N. Instrument Kits

October 25, 2022

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 Health Technology 6 (OHT 6: Orthopedic Devices)
Reviewing Division	Division of Health Technology 6 B (Spinal Devices)

PREDICATE DEVICE INFORMATION

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

SUBJECT DEVICE INDICATIONS FOR USE STATEMENT

Indications for Use for Epikut Long 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 Long Surgical Kit and the associated instruments is 422 grams.
The weight of the empty Epikut Long Surgical Kit is 310 grams.

SUBJECT DEVICE DESCRIPTION

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

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

SUMMARY OF NONCLINICAL TESTING

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

Summary of Nonclinical Testing Table

Test Methodology	**Purpose**	**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.	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)	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.	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.	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.	Pass
Biocompatibility of Subject Device Cytotoxicity testing ANSI/AAMI/ISO 10993-5 ANSI/AAMI/ISO 10993-12 *Referenced from K201688 and K212404*	The purpose of this test is to evaluate the cytotoxicity potential of the test article using an in vitro cell culture assay.	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 this 510(k) submission, S.I.N. Instrument Kits, is as safe, as effective, and perform as well as or better than the legally marketed predicate devices cleared under K201688 and K212404.