October 20, 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: K211921
Trade/Device Name: S.I.N. Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: September 17, 2021
Received: September 20, 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); 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,

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K211921

Device Name

S.I.N. Dental Implant System

Indications for Use *(Describe)*

S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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
K211921
S.I.N. - Sistema de Implante Nacional S.A.
S.I.N Dental Implant System

October 19, 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. Dental Implant System
Common Names	Endosseous dental implant
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code	DZE
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1 B (Dental Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K200992, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.

Additional Predicate Devices
K193096, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.
K170398, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.

INDICATIONS FOR USE STATEMENT

S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to add components to the S.I.N. Dental Implant System components cleared in K200992, K193096, and K170398.

This submission includes dental implants Epikut CM with a Morse taper (CM) abutment interface and a double acid-etched endosseous surface, and Epikut Plus CM implants with an endosseous surface produced by double acid-etching followed by application of a hydroxyapatite coating (HA^{nano}). These implant endosseous surfaces are identical to those cleared in K200992.

This submission also includes dental implants Epikut HE with an external hexagon (HE) abutment interface and a double acid-etched endosseous surface, and Epikut Plus HE implants with an endosseous surface produced by double acid-etching followed by application of a hydroxyapatite coating (HA^{nano}). These implant endosseous surfaces also are identical to those cleared in K200992.

The subject device dental implants are summarized in the following table.

Implant Lines	**Body Ø, mm**	**Platform Ø, mm**	**Lengths, mm**					
Epikut CM **Epikut Plus CM**	3.5	3.5		8.5	10	11.5	13	15
	3.8	3.8		8.5	10	11.5	13	15
	4.5	4.5		8.5	10	11.5	13	15
	5.0	5.0		8.5	10	11.5	13	15
Epikut HE **Epikut Plus HE**	3.5	3.65	7.0	8.5	10	11.5	13	15
	4.5	4.5		8.5	10	11.5	13	15
	5.0	5.0	7.0	8.5	10	11.5	13	15

All subject device dental implants are manufactured from unalloyed titanium conforming to ASTM F67. The acid etching procedure is applied to all subject device dental implants. The acid etching process in this submission is identical to the process used to manufacture the dental implants cleared in K200992, K193096, and K170398. The Epikut Plus CM and Epikut Plus HE implants have the identical HA^{nano} surface treatment cleared in K200992 and K193096.

The subject device dental implants are compatible with abutments and prosthetic components cleared previously in K200992, K193096, K170398, K170392, and K051859. Epikut HE and Epikut Plus HE dental implants are not for use with angled abutments.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included: gamma irradiation sterilization for all subject devices (to a sterility assurance level of 10^{-6} by selecting and substantiating a 25 kGy dose using method VDmax25, according to ISO 11137-1 and ISO 11137-2, referenced from K200992);

bacterial endotoxin testing (referenced from K200992) including *Limulus* amebocyte lysate (LAL) test according to ANSI/AAMI ST72 on samples of water used in manufacturing on a weekly basis and on samples from sterilized product on a quarterly basis to demonstrate all sterile product meets a limit of ≤ 20 EU/device;

shelf life testing (referenced from K200992) including testing of samples after 4 years of real time aging according to ASTM F1929 and F88/F88M (packaging sterile barrier) and sterility testing of product;

biocompatibility testing for the HA_{nano} hydroxyapatite coating leveraged from K200992 and provided in K170392 included ISO 10993-3 (genotoxicity), ISO 10993-5 (cytotoxicity), ISO 10993-6 (implantation), ISO 10993-10 (sensitization, irritation), and ISO 10993-11 (systemic toxicity);

and characterization of the HA_{nano} hydroxyapatite coating leveraged from K200992 and provided in K170392 included scanning electron microscopy (SEM), x-ray photoelectron spectroscopy (XPS), transmission electron microscopy (TEM), x-ray diffraction (XRD), and testing of the adherence of the coating.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the predicate device and the additional predicate devices listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the additional predicate devices.

The Indications for Use Statement (IFUS) for the subject device is identical to that of the primary predicate K200992, and is very similar to the IFUS of the additional predicates K193096 and K170398. The minor difference between the IFUS for the subject device and the additional predicate K193096 is the language concerning CAD-CAM abutments in K193096. The minor difference between the IFUS for the subject device and the additional predicate K170398 is the language concerning Revolution Company implants in K170398. These minor differences do not impact safety or effectiveness because all IFUS express equivalent intended use to facilitate functional and esthetic rehabilitation of the edentulous mandible or maxilla.

The subject device Epikut CM and Epikut Plus CM implants are similar in design and sizes to the Strong SW and Strong SW Plus implants, respectively, cleared in K200992. The subject device Epikut CM and Epikut Plus CM implants and the Strong SW and Strong SW Plus implants have the same 11.5° internal Morse taper abutment connection, and are provided in the same sizes of body/platform diameters and overall lengths. The subject device Epikut CM implants and the Strong SW implants have the same acid-etched endosseous surface treatment. The subject device Epikut Plus CM implants and the Strong SW Plus implants have the same acid-etched and HA^{nano} endosseous surface treatment.

The subject device Epikut HE implants are similar in design and sizes to the Strong SW HE implants cleared in K170398. The subject device Epikut HE implants and the Strong SW HE implants have the external hexagon abutment interface and are provided in the same sizes of body/platform diameters and overall lengths. The subject device Epikut HE implants and the Strong SW HE implants have the same acid-etched endosseous surface treatment.

The subject device Epikut Plus HE implants are similar in design and sizes to the Strong SW HE Plus

implants cleared in K193096. The subject device Epikut Plus HE implants and the Strong SW HE Plus implants have the external hexagon abutment interface and are provided in the same sizes of body/platform diameters and overall lengths. The subject device Epikut Plus HE implants and the Strong SW HE Plus implants have the same acid-etched and HA^{nano} endosseous surface treatment.

All subject device dental implants are manufactured from the same unalloyed titanium and have the same acid-etched surface treatment as the dental implants cleared in K200992, K193096, and K170398. In addition to the acid-etch, the subject device Epikut Plus CM and Epikut Plus HE implants also have the identical HA^{nano} surface cleared in K200992 and K193096.

Minor differences in the exact dimensions of the subject device components as compared to those of the primary predicate device and additional predicate devices do not impact safety, effectiveness, or substantial equivalence. The cross sections of the subject device implants (Epikut CM and Epikut Plus CM) were compared to the cross sections of the worst-case implants cleared in K200992. The critical dimension evaluated was the minimum wall thickness from the top of the implant down to the potting level for ISO 14801 testing. This analysis demonstrated that the subject device CM implants do not introduce an additional or new worst-case construct that requires mitigation by additional mechanical testing. Therefore, the fatigue testing according to ISO 14801 provided in K200992 is applicable to the subject device CM implants.

All subject device implants components are provided sterile by gamma irradiation, the same sterilization method used in K200992, K193096, and K170398.

CONCLUSION

The subject device, the primary predicate device, and the additional predicate devices have the same intended use, have similar technological characteristics, and are made of identical or similar materials. The subject device, the primary predicate, and the additional predicate devices encompass the same range of physical dimensions, are packaged in similar materials, and are sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Table of Substantial Equivalence

	Subject Device	Primary Predicate Device	Additional Predicate	Additional Predicate
	S.I.N. Dental Implant System **S.I.N. - Sistema de Implante Nacional S.A.**	**K200992** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K193096** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K170398** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**
Indications for Use Statement	S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. All digitally-designed custom abutments for use with Interface CAD-CAM abutments are to be sent to a S.I.N.-validated milling center for manufacture.	S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Revolution Compact with a 6 mm length is intended for delayed loading only.
Reason for Predicate Device	**Not applicable**	**Implant design; HA^{nano} implant surface**	**Implant design; HA^{nano} implant surface**	**Implant design**
Product Codes	DZE	DZE, NHA	DZE, NHA	DZE, NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Implant Designs				
Prosthetic Interface Connections	Morse taper (CM, 11.5°) and External Hex (HE)	Morse taper (CM, 11.5°)	Morse taper (CM, 16°) and External Hex (HE)	External hex (HE), and Internal Hex (HI)
Body/Platform Diameters, mm Lengths, mm Interface	**Epikut CM** 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 8.5, 10, 11.5, 13, 15 Morse taper interface (CM, 11.5°)	**Strong SW** 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 8.5, 10, 11.5, 13, 15 Morse taper interface (CM, 11.5°)		
Body/Platform Diameters, mm Lengths, mm Interface	**Epikut Plus CM** 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 8.5, 10, 11.5, 13, 15 Morse taper interface (CM, 11.5°)	**Strong SW Plus** 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 8.5, 10, 11.5, 13, 15 Morse taper interface (CM, 11.5°)		
Body/Platform Diameters, mm Lengths, mm Interface	**Epikut HE** 3.5/3.65; 4.5/4.5; 5.0/5.0 7*, 8.5, 10, 11.5, 13, 15 ** no 7 mm length for 4.5 mm body* External hex interface (HE)			**Strong SW HE** 3.5/3.65; 3.75/4.1; 4.0/4.1; 4.5/4.5; 5.0/5.0 7*, 8.5, 10, 11.5, 13, 15 ** no 7 mm length for 4.5 mm body* External hex interface (HE)
Body/Platform Diameters, mm Lengths, mm Interface	**Epikut Plus HE** 3.5/3.65; 4.5/4.5; 5.0/5.0 7*, 8.5, 10, 11.5, 13, 15 ** no 7 mm length for 4.5 mm body* External hex interface (HE)		**Strong SW HE Plus** 3.5/3.65; 3.75/4.1; 4.0/4.1; 4.5/4.5; 5.0/5.0 7*, 8.5, 10, 11.5, 13, 15 ** no 7 mm length for 4.5 mm body* External hex interface (HE)	
Implant Material	All implants: unalloyed titanium, ASTM F67	All implants: unalloyed titanium, ASTM F67	All implants: unalloyed titanium, ASTM F67	All implants: unalloyed titanium, ASTM F67
Implant Endosseous Surface	All implants: acid-etched; HA^{nano} applied to the Epikut Plus CM and Epikut Plus HE implants	All implants: acid-etched; HA^{nano} applied to the Strong SW implants	All implants: acid-etched; HA^{nano} applied to the Strong SW implants	All implants: acid-etched
Implant Placement	CM designs: 1.5 mm intra-bony (sub-crestal) HE designs: at bone level (at the crest)	CM designs: 1.5 mm intra-bony (sub-crestal)	HE designs: at bone level (at the crest)	HE designs: at bone level (at the crest)
How Provided				
Implants	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation
Usage	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use