S.I.N. - Sistema de Implante Nacional S.A. 10/27/22
% Kevin Thomas
Vice President & Director of Regulatory Affairs
PaxMed International, LLC
12264 EL Camino Real, Suite 400
San Diego, California 92130

Re: K222231
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, NHA
Dated: September 26, 2022
Received: September 26, 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,

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)*
K222231

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.

S.I.N. Dental Implant System implants with lengths of 18, 20, 22, or 24 mm be tilted up to 30°. When used in the mandible or maxilla with implants with lengths of 18, 20, 22, or 24 mm at an angulation of 30°, a minimum of four implants must be used and must be splinted. When placed in the maxilla with lengths of 18, 20, 22, or 24 mm at angulations between 0° and less than 30°, the S.I.N. Dental Implant System implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

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
K222231
S.I.N. - Sistema de Implante Nacional S.A.
S.I.N Dental Implant System

October 27, 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. 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
K211921, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.

Additional Predicate Devices
K203725, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.
K050406, NOBELSPEEDY™ Implants, Nobel Biocare USA LLC
K170392, 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 implants with lengths of 18, 20, 22, or 24 mm be tilted up to 30°. When used in the mandible or maxilla with implants with lengths of 18, 20, 22, or 24 mm at an angulation of 30°, a minimum of four implants must be used and must be splinted. When placed in the maxilla with lengths of 18, 20, 22, or 24 mm at angulations between 0° and less than 30°, the S.I.N. Dental Implant System implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to add components to the S.I.N. Dental Implant System, which includes components cleared previously in K211921, K200992, and K170392.

This submission includes dental implants Epikut S with a Morse taper (CM) abutment interface and an acid-etched endosseous surface, and Epikut S Plus implants with an endosseous surface produced by acid-etching followed by application of a hydroxyapatite coating (HA^{nano}). The implant design and endosseous surfaces are nearly identical to the Epikut CM and Epikut Plus CM implants cleared in K211921, with the exception of the implant-abutment connection (subject device 16° Morse taper, K211921 11.5° Morse taper), the additional body/platform diameter (4.0 mm), and the longer lengths (18, 20, 22, and 24 mm).

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

Implant Lines	Body Ø, mm	Platform Ø, mm	Lengths, mm
Epikut S **Epikut S Plus**	3.5	3.5	8.5, 10, 11.5, 13, 15
	3.8	3.8	8.5, 10, 11.5, 13, 15, 18, 20, 22, 24
	4.0	4.0	8.5, 10, 11.5, 13, 15, 18, 20, 22, 24
	4.5	4.5	8.5, 10, 11.5, 13, 15, 18, 20, 22, 24
	5.0	5.0	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 K211921, and the HA^{nano} surface treatment is identical to that cleared in K211921.

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 K211921 and K203725);

bacterial endotoxin testing (referenced from K211921) 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 K211921) 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;

biological evaluation was performed according to ISO 10993-1 and test results leveraged from reference device, K211921 to support biocompatibility of the subject device;

characterization of the HA^{nano} hydroxyapatite coating leveraged from K211921 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;

non-clinical analysis and testing to evaluate the metallic subject devices in the MR environment according to ASTM F2052 (magnetically induced displacement force), ASTM F2213 (magnetically induced torque), ASTM F2182 (RF induced heating), and ASTM F2119 (image artifact), and the FDA guidance document *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* (issued May 2021); and

engineering analysis provided in this submission demonstrated that the subject device implants, in combination with compatible previously-cleared abutments, do not create a new worst-case construct, and that previous mechanical testing from K200992 is applicable to the subject device implants.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The primary predicate device K211921 is in support of substantial equivalence for the implant designs, materials, manufacturing, and sterilization. The additional predicate device K203725 is for the implant lengths of 18 mm to 24 mm, and the additional predicate K050406 is in support of substantial equivalence of the Indications for Use statement for implants tilted up to 30°, as described below. The additional predicate device K170392 is in support of substantial equivalence of the subject device implant-abutment connection (16° Morse taper).

The Indications for Use Statement (IFUS) for the subject device includes language concerning placement in the maxillary or mandibular arches and regarding immediate loading that is identical to the language in K211921, K203725, and K170392. The IFUS for the subject device also includes language similar to that included in K203725 regarding longer length implants.

The IFUS for the subject device includes language that implants with lengths of 18 mm to 24 mm may be tilted up to 30°, and language that requires for an angulation of 30°, a minimum of four (4) implants must be used and must be splinted. This language is similar to the language in the IFUS of the predicate device K050406. The IFUS for the subject device also includes language that implants with lengths of 18 mm to 24 mm placed at angulations between 0° and less than 30° are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. This language is nearly identical to language in the IFUS of the predicate device K203725.

Differences between the IFUS for the subject device and the predicate devices include: language in K203725 regarding zygomatic implants that is not relevant to the subject device; language in K050406 regarding features of the implants (grooves and surface treatment) that is not relevant to the subject device, and language for tilting of the implants up to 45°; and language in K170392 regarding implant lengths less than 7 mm that is not relevant to the subject device.

Subject Device Dental Implants

The subject device Epikut S and Epikut S Plus implants have nearly identical designs (except for the Morse taper connection and 18-24 mm lengths), materials, and manufacturing as used for the Epikut CM and Epikut Plus CM implants cleared in K211921. The subject device Epikut S and Epikut S Plus implants have the same 16° internal Morse taper abutment connection and are provided in the same range of body/platform diameters as the implants cleared in K170392; the subject implants are provided in an additional body/platform diameter of 4.0/4.0, which is within the range of the implant sizes cleared in K170392. The subject device implant lengths 18 mm to 24 mm are the same as implants cleared in K203725.

All subject device dental implants are manufactured from the same unalloyed titanium and all have the same acid-etched surface treatment used for the dental implants cleared in K211921 and K170392. The subject device Epikut S Plus implants have the same acid-etched and HA^{nano} endosseous surface treatment as used for implants cleared in K211921.

All subject device implants are provided sterile by gamma irradiation. The subject devices have the same sterilization method, packaging, and sterile barrier shelf life as devices cleared in K211921, K203725, and K170392.

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**	**Additional Predicate**
	K222231 **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K211921** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K050406** **NOBELSPEEDY™ Implants** **Nobel Biocare USA LLC**	**K203725** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K170392** **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 implants with lengths of 18, 20, 22, or 24 mm be tilted up to 30°. When used in the mandible or maxilla with implants with lengths of 18, 20, 22, or 24 mm at an angulation of 30°, a minimum of four implants must be used and must be splinted. When placed in the maxilla with lengths of 18, 20, 22, or 24 mm at angulations between 0° and less than 30°, the S.I.N. Dental Implant System implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.	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.	NOBELSPEEDY™ Implants are root-form endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NOBELSPEEDY™ Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare NOBELSPEEDY™ Implants may be placed immediately and put into immediate function providing that the initial stability requirements detailed in the surgical manuals are satisfied. NOBELSPEEDY™ Implants are indicated for use in soft bone or whenever immediate or early loading is applied. The NOBELSPEEDY™ Implants incorporate a groove on the implant thread and are preferred over models without the groove in these soft bone indications because bone forms more rapidly in the groove than on other parts of the implant resulting in increased stability when compared to non-grooved implants. In addition, the NOBELSPEEDY™ Implants are preferred in these soft bone indications because bone formation on the TiUnite® surface is more rapid and greater than on machined surface implants resulting in better maintenance of initial implant stability, faster and stronger osseointegration, and higher success rates. NOBELSPEEDY™ Implants may be tilted up to 45°. When used with angulations between 30° and 45° a minimum of four implants must be used and splinted.	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 implants with lengths of 18, 20, 22, or 24 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. S.I.N. Dental Implant System Zygomatic implants are intended for placement in the maxillary arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System Zygomatic implants are intended for immediate loaded 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. Implants with lengths less than 7 mm are intended for delayed loading only.
Reason for Predicate Device	Not applicable	Implant design; materials; manufacturing; sterilization	Indications for Use for implants tilted up to 45°	Implant design, lengths 18 mm to 24 mm; materials; manufacturing; sterilization	Implant designs; materials; manufacturing; sterilization
Product Codes	DZE, NHA	DZE	DZE	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	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Implant Designs					
Prosthetic Interface Connections	Morse taper (CM, 16°)	Morse taper (CM, 11.5°) and External Hex (HE)	*Not stated in 510(k) Summary*	External hex (HE)	Morse taper (CM, 16°)
Body/Platform Diameters, mm Lengths, mm Interface	**Epikut S** 3.5/3.5, 3.8/3.8; 4.0/4.0; 4.5/4.5, 5.0/5.0 8.5 – 15, all body diameters 18–24, for diameters 3.8, 4.0, 4.5 Morse taper interface (CM, 16°)	**Epikut CM** 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 8.5 – 15 Morse taper interface (CM, 11.5°)	*Not stated in 510(k) Summary*	**Strong SW HE** 3.75/4.1 18, 20, 22, 24 External hex (HE)	**Strong SW CM** 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 8.5 –15, all body diameters Morse taper interface (CM, 16°)
Body/Platform Diameters, mm Lengths, mm Interface	**Epikut S Plus** 3.5/3.5, 3.8/3.8; 4.0/4.0; 4.5/4.5, 5.0/5.0 8.5–15, all body diameters 18–24, for diameters 3.8, 4.0, 4.5 Morse taper interface (CM, 16°)	**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°)			
Implant Material	All implants: unalloyed titanium, ASTM F67	All implants: unalloyed titanium, ASTM F67	*Not stated in 510(k) Summary*	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 S Plus implants	All implants: acid-etched; HA^{nano} applied to the Epikut Plus CM implants	TiUnite® surface	All implants: acid-etched	All implants: acid-etched
How Provided					
Implants	Sterile by gamma irradiation	Sterile by gamma irradiation	*Not stated in 510(k) Summary*	Sterile by gamma irradiation	Sterile by gamma irradiation
Usage – All Components	Single patient, single use	Single patient, single use	*Not stated in 510(k) Summary*	Single patient, single use	Single patient, single use