April 6, 2023

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: K230069
Trade/Device Name: S.I.N. Dental Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 9, 2023
Received: January 10, 2023

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,

Andrew I. Steen -S

Andrew I. 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)*

K230069

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.

All digitally-designed custom abutments for use with Pre-Milled CAD-CAM Abutments are to be sent to a S.I.N.-validated milling center for manufacture.

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
K230069
S.I.N. - Sistema de Implante Nacional S.A.
S.I.N Dental Implant System

April 6, 2023

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	Dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Dental and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K193096, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.

Reference Devices
K221453, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.
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.
K200992, 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.

All digitally-designed custom abutments for use with Pre-Milled CAD-CAM Abutments are to be sent to a S.I.N.-validated milling center for manufacture.

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 K221453, K222231, K211921, K193096, and K170392.

This submission adds Pre-Milled CAD-CAM Abutments to the S.I.N. Dental Implant System. The subject device abutments are provided with 11.5° CM and 16° CM connections compatible with the above S.I.N. dental implants.
The design parameters for the CAD-CAM fabrication of patient-specific abutments from Pre-Milled CAD-CAM Abutments are the same for the 11.5° CM implant connection and the 16° CM implant connection. The design limit parameters are:

- Minimum wall thickness – 0.55 mm
- Minimum post height for single-unit restoration – 4.0 mm
- Minimum gingival height – 0.55 mm
- Maximum gingival height – 3.5 mm
- Minimum prosthetic platform diameter – 3.5 mm
- Maximum prosthetic post height – 6 mm
- Maximum angulation – 30°

The subject device abutments are compatible with previously cleared S.I.N. Dental Implant System implant bodies summarized in the following table.

Compatible Previously Cleared Implants, 11.5° CM	**510(k) Number**
Unitite Implant, body Ø 3.5 mm, 4.3 mm, 5.0 mm	K170392
Implant Strong SW, body Ø 3.5 mm, 3.8 mm, 4.5 mm, 5.0 mm	K200992
Implant Strong SW Plus, body Ø 3.5 mm, 3.8 mm, 4.5 mm, 5.0 mm	
Implant Tryon CM Conical, body Ø 3.5 mm, 4.0 mm, 5.0 mm	
Implant Tryon CM Cylindrical Body and Conical Apex, body Ø 3.5 mm, 3.75 mm, 4.0 mm	
Implant Tryon CM Cylindrical, body Ø 3.5 mm, 3.75 mm, 4.0 mm, 5.0 mm	
Implant Epikut CM, body Ø 3.5 mm, 3.8 mm, 4.5 mm, 5.0 mm	K211921
Implant Epikut Plus CM, body Ø 3.5 mm, 3.8 mm, 4.5 mm, 5.0 mm	
Implant Epikut CM, body Ø 3.8 mm, 4.0 mm, 4.5 mm	K221453
Implant Epikut Plus CM, body Ø 3.8 mm, 4.0 mm, 4.5 mm	

Compatible Previously Cleared Implants, 16° CM	510(k) Number
Strong SW CM Implant, body Ø 3.5 mm, 3.8 mm, 4.5 mm, 5.0 mm	K170392
Strong SW CM Plus Implant, body Ø 3.5 mm, 3.8 mm, 4.5 mm, 5.0 mm	K193096
Implant Epikut S, body Ø 3.5 mm, 3.8 mm, 4.0 mm, 4.5 mm, 5.0 mm	K222231
Implant Epikut S Plus, body Ø 3.5 mm, 3.8 mm, 4.0 mm, 4.5 mm, 5.0 mm	

All subject device abutments are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136, and are to be used with compatible abutment screws previously cleared in K170392. All subject device abutments are provided non-sterile and are to be moist heat sterilized by the end user.

PERFORMANCE DATA

Non-clinical data submitted or referenced to demonstrate substantial equivalence included:

- provided in this submission was moist heat sterilization for subject devices provided non-sterile to the end user, validated to a sterility assurance level of 10^{-6} by the overkill method according to ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO TIR 17665-2;
- referenced from K170398 was biocompatibility testing according to ISO 10993-5 (cytotoxicity) for the abutment material ASTM F136;
- referenced from K221453 was non-clinical analysis and testing to evaluate the metallic subject devices and compatible dental implants 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);
- provided in this submission was engineering analysis to demonstrate that the subject device abutments, in combination with compatible previously cleared dental implants, do not create a new worst-case construct in terms of mechanical testing according to ISO 14801; and
- referenced from K200992 was mechanical testing conducted according to ISO 14801 to support the performance of the subject device abutments, in conjunction with the engineering analysis provided in this submission.

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 primary predicate device and the reference 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 reference devices.

The primary predicate device K193096 is in support of substantial equivalence of the Indications for Use including CAD-CAM abutments, abutment designs, materials, manufacturing, sterilization, and compatible implants. The reference devices K221453, K222231, K211921, K200992, and K170392 are in support of substantial equivalence of the Indications for Use including CAD-CAM abutments (K221453), abutment designs, materials, manufacturing, sterilization, and compatible implants.

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 K193096. The IFUS for the subject device also includes language concerning CAD-CAM abutments and validated milling centers that is identical, besides the trade name, to that included in K193096.

Differences between the IFUS for the subject device and the reference devices include: language in K221453 and K222231 regarding indications for implants with lengths of 18-24 mm that is not relevant to the subject device; language in K170392 regarding implant lengths less than 7 mm that is not relevant to the subject device; and the IFUS for K222231, K211921, K200992, and K170392 do not contain language regarding CAD-CAM abutments and validated milling centers.

The subject device abutments with the 11.5° CM interface are compatible with implants cleared in K200992, K221453, K211921, and K170392 in terms of the abutment-implant connection. The subject device abutments with the 11.5° CM interface in final finished form are substantially equivalent to the Abutment Cemented Angled Indexed SIT cleared in K200992 in terms of material and design limit parameters including prosthetic platform diameter, maximum gingival height, and maximum angulation.

The subject device abutments with the 16° CM interface are compatible with implants cleared in K222231, K193096, and K170392 in terms of the abutment-implant connection. The subject device abutments with the 16° CM interface in final finished form are substantially equivalent to the Abutment Cemented Morse Angled cleared in K200992 in terms of material and design limit parameters including prosthetic platform diameter, maximum gingival height, and maximum angulation.

The subject device abutments are to be end user sterilized; validated sterilization instructions are provided in the Instructions for Use. Similar components to be end-user sterilized (abutments manufactured from Ti-6Al-4V alloy material) were cleared in K221453, K193096, and K170392.

The subject device abutments are packaged in a polyethylene terephthalate blister pack with a Tyvek cover. The Tyvek cover for the blister pack is printed with the appropriate label for the corresponding component. This is the same packaging used for similar abutments (provided non-sterile) in K221453.

An engineering rationale was provided to demonstrate that the use of the subject device abutments in combination with the compatible implants raise no new risks and that mechanical testing data provided in a prior submission (K200992) are applicable to the subject abutments.

CONCLUSION

The subject device, the primary predicate device, and the reference 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 reference 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 primary predicate device and the reference devices listed above.

Table of Substantial Equivalence

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	K230069 **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.**	**K200992** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K221453** **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 (IFUS)	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 Pre-Milled 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. 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.	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 may 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. 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. Implants with lengths less than 7 mm are intended for delayed loading only.
Reason for Predicate Device	Not applicable	IFUS including CAD-CAM abutments and validated milling centers; Compatible implants	Abutment designs; materials; manufacturing; sterilization; Compatible implants	IFUS including CAD-CAM abutments and validated milling centers; Compatible implants	Abutment designs; materials; manufacturing; sterilization Compatible implants
Product Codes	NHA	DZE, NHA	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	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Abutment Designs					
CM 11.5° interface	**Pre-Milled Blank Abutments** CM 11.5° interface Minimum post height for single-unit restoration: 4 mm Prosthetic platform Ø: 3.5 mm (min) Gingival height: 3.5 mm (max), 0.55 mm (min) Angle: 30° (max) Indexed		**Abutment Cemented Angled Indexed SIT** CM 11.5° interface Prosthetic platform Ø: 3.3, 4.5 mm Gingival height: 1.5-3.5 mm Angle: 17°, 30° Indexed		
CM 16° interface	**Pre-Milled Blank Abutments** CM 16° interface Minimum post height for single-unit restoration: 4 mm Prosthetic platform Ø: 3.5 mm (min) Gingival height: 3.5 mm (max), 0.55 mm (min) Angle: 30° (max) Indexed		**Abutment Cemented Morse Angled** CM 16° interface Prosthetic platform Ø: 3.3, 4.5 mm Gingival height: 1.5-3.5 mm Angle: 17°, 30 Indexed		
Abutment Materials	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	K230069 **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.**	**K200992** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K221453** **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.**
Compatible Implants					
CM 11.5° Connection			**Strong SW and** **Strong SW Plus** Body/platform Ø 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 mm Lengths 8.5-15 mm	**Epikut CM** **Epikut Plus CM** Body/platform Ø 3.8/3.8; 4.0/4.0; 4.5/4.5 mm Lengths 18-24 mm	**Unitite** Body/platform Ø 3.5/3.5; 4.3/4.3, 5.0/5.0 mm Lengths 8.5-15 mm
			Tryon CM Conical Body/platform Ø 3.5/3.5, 4.0/4.0; 5.0/5.0 mm Lengths 8.5-15 mm		
			Tryon CM Cylindrical Body and Conical Apex Body/platform Ø 3.5/3.5, 3.8/3.8, 4.5/4.5; 5.0/5.0 mm Lengths 8.5-15 mm		
			Tryon CM Cylindrical Body/platform Ø 3.5/3.5, 3.75/3.75, 4.0/4.0; 5.0/5.0 mm Lengths 7-15 mm		
CM 16° Connection		**Strong SW CM Plus** Body/platform Ø 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 mm Lengths 8.5-15 mm			**Strong SW CM** Body/platform Ø 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 mm Lengths 8.5-15 mm
How Provided					
Abutments	Non-sterile, to be sterilized by moist heat by the end user	Sterile by gamma irradiation and Non-sterile, to be sterilized by moist heat by the end user	Sterile by gamma irradiation	Sterile by gamma irradiation and Non-sterile, to be sterilized by moist heat by the end user	Sterile by gamma irradiation and Non-sterile, to be sterilized by moist heat by the end user
Usage – All Components	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	*Not stated in 510(k) Summary*