December 5, 2017

S.I.N. - Sistema de Implante Nacional S.A.
Linda K. Schulz
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K170392
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: November 2, 2017
Received: November 3, 2017

Dear Linda K. Schulz:

This letter corrects our substantially equivalent letter of December 1, 2017.

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170392

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. Implants with lengths less than 7 mm are intended for delayed loading only.

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
S.I.N. - Sistema de Implante Nacional S.A.
S.I.N. Dental Implant System
K170392

December 1, 2017

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	Dênis Oliveira Quality and Regulatory Manager
Representative/Consultant	Linda K. Schulz, BSDH, RDH 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: lschulz@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	S.I.N. Dental Implant System
Common Name	Dental implant Dental implant abutment
Classification Name	Implant, endosseous, root form Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640, 21 CFR 872.3630, Class II
Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate		
K051859	Sistema de Implante Nacional Dental Implant System	Sistema de Implante Nacional, Ltda.
Reference Predicates		
K120414	OsseoSpeed™ Plus	Astra Tech AB
K072570	NobelActive Multi Unit Abutment	Nobel Biocare AB
K081653	MDI MII 2.9 mm Implants	IMTEC Corporation
K101225	Promimic Dental Implant	Promimic AB
K092035	Bicon Implants with a 2.5mm Internal Connection	Bicon, L.L.C

INDICATIONS FOR USE

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.

DEVICE DESCRIPTION

The subject device consists of four Morse taper connection product lines: Unitite Slim, Unitite, Unitite Compact, and Strong SW CM. All implants are threaded cylindrical root-form designs. The Unitite product line is provided with an acid-etched and HA surface, the Strong SW CM is provided with an acid-etched surface. Each product line has abutments available in multiple designs (temporary, cementable, angled, UCLA, ball, multi-unit). Subject device abutments are straight only.

Unitite implants are available in six implant body diameters (2.9, 3.5, 4.0, 4.3, 5.0 and 6.0 mm) and eight lengths (5, 6, 7, 8.5, 10, 11.5, 13, and 15 mm). Strong SW CM implants are available in four implant diameters (3.5, 3.8, 4.5, 5.0 mm) and five lengths (8.5, 10, 11.5, 13, and 15 mm). Unitite abutments are available in five prosthetic platform diameters (3.3, 3.5, 4.0, 4.5, and 4.8 mm). Strong SW CM abutments are available in four prosthetic platform diameters (3.3, 3.5, 4.5 and 4.8 mm). Subject Device components are made of commercially pure titanium, titanium alloy, cobalt-chromium, or polycarbonate.

IMPLANT	Body Diameter mm	Platform Diameter mm	Length mm
Unitite Slim	2.9	2.9	10, 11.5, 13
Unitite	3.5	3.5	8.5, 10, 11.5, 13, 15
	4.3	4.3	8.5, 10, 11.5, 13, 15
	5.0	5.0	8.5, 10, 11.5, 13, 15
Unitite Compact	4.0	4.0	5, 6, 7
	5.0	5.0	5, 6, 7
	6.0	6.0	5, 6, 7
Strong SW 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

PERFORMANCE DATA

Non-clinical testing data submitted or relied upon to demonstrate substantial equivalence included: radiation sterilization validation according to ISO 11137-1 and 11137-2 and steam sterilization validation according to ISO 17665-1 and ISO 17665-2, demonstrating a sterility assurance level (SAL) of 10^{-6}; *Limulus* amebocyte lysate (LAL) testing according to AANSI/AAMI ST 72; Shelf life testing according to ASTM F1980, ASTM F1929, and ASTM F88/F88M; biocompatibility testing according to ISO 10993-3 (genotoxicity), ISO 10993-5 (cytotoxicity), ISO 10993-6 (implantation), ISO 10993-10 (sensitization and irritation), and ISO 10993-11 (systemic toxicity) demonstrating acceptable biocompatibility; surface area analysis showing substantial equivalence to a predicate; and performance testing for insertion surface abrasion to show substantial equivalence to the predicate.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent in indications and design principles to the predicate devices shown above. Below are summary tables comparing the Indications for Use and the technological characteristics of the subject device and the predicate devices.

Comparison of Indications for Use Statements

Subject Device	
K170392 S.I.N. Implant System SIN – Sistema de Implante Nacional S.A.	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.
Primary Predicate Device	
K051859 Sistema de Implante Nacional Dental Implant System SIN – Sistema de Implante Nacional, Ltda.	The Sistema de Implante Nacional Dental Implant System is intended to be surgically placed in the bone of the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures. Implants may be placed immediately after tooth extraction or following bone healing. Restorations supported by two or more Sistema de·1mplante Nacional implants may be loaded immediately after implant placement if primary implant stability has been achieved.
Reference Predicate Devices	
K120414 OsseoSpeed™ Plus Astra Tech AB	Implants: The Astra Tech Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • replacing single and multiple missing teeth in the mandible and maxilla, • immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge, • especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective, • immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm, or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate. The intended use for OsseoSpeed™ Plus 3.0S is limited to replacement of maxillary lateral incisors and mandibular incisors. Abutments: Astra Tech Implant System Plus abutments are intended to be used in conjunction with Astra Tech Implant System Plus in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures. Atlantis Abutments: The Atlantis™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous; patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous; implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous; patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant.
K072570 NobelActive Multi Unit Abutment Nobel Biocare AB	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and intended for use as an aid in prosthetic rehabilitation.
K081653 MDI MII 2.9 mm Implants IMTEC Corporation	The MII Implant is intended to support single or multi-unit restorations in both long-term and temporary applications throughout the maxillary and mandibular arches. The MII implant is indicated for immediate loading when good primary stability is achieved. Additionally, this device will permit stability and long term fixation of upper and lower dentures in edentulous cases.
K101225 Promimic Dental Implant Promimic AB	The Promimic AB, Promimic Dental Implant is intended for surgical placement into the bone of upper/lower jaw arches as a permanent anchorage for prosthetic devices and to restore chewing function. The Promimic Dental Implant can be immediately loaded only with good primary stability and appropriate occlusal loading. The Promimic Dental Implants are only to be used with straight abutments.
K092035 Bicon Implants with a 2.5mm Internal Connection Bicon, L.L.C.	The Bicon implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement.

Comparison of Technological Characteristics

	Subject Device	**Primary Predicate Device**	**Reference Predicate Devices**				
		K051859	K120414	K072570	K081653	K101225	K092035
	S.I.N. Implant System	Sistema de Implante Nacional Dental Implant System	OsseoSpeed™ Plus	NobelActive Multi Unit Abutment	MDI MII 2.9 mm Implants	Promimic Dental Implant	Bicon Implants with a 2.5mm Internal Connection
	S.I.N. – Sistema de Implante Nacional S.A.	S.I.N. – Sistema de Implante Nacional, Ltda.	Astra Tech AB	Nobel Biocare AB	IMTEC Corporation	Promimic AB	Bicon, L.L.C.
DESIGN							
Prosthesis Attachment	Screw-retained Cement-retained	Screw-retained Cement-retained	Screw-retained Cement-retained	Screw-retained	Cement-retained	Screw-retained Cement-retained	Screw-retained Cement-retained
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Implant/Abutment Interface	External Internal	External Internal	Internal	Internal	One Piece	External	Internal
Implant Diameter, mm	2.9 – 6.0	3.25 – 6.3	3.0 – 5.4	NA	2.9	3.75	4.0 – 4.5
Implant Length, mm	5.0 – 15	7.0 – 18	6.0 – 17	NA	10 – 18	8.5 – 15	5 – 11
Abutment Platform Diameter, mm	3.3 – 4.8 (Prosthetic Ø)	3.4 – 5.5 (Prosthetic Ø)	3.0 – 5.4	NP, RP	NA	3.75	4.0 – 6.5
Abutment Angle	0°	0° - 19°	0° - 30°	0° - 30°	0°	0°	0°
MATERIAL							
Implant	CPTi Gr 4	CPTi Gr 4	CPTi Gr 4	NA	Titanium Alloy	CPTi Gr 4	TI6AL4V
Surface	Acid-Etched HA	Acid-Etched	OsseoSpeed™	NA	Unknown	HA	HA, TPS, Integra Ti, NanoTite™
Abutment	Ti-6Al-4V CoCr	CPTi Gr 2 Ti-6Al-4V CoCr Gold alloy	Ti-6Al-4V Zirconia Gold alloy PEEK	Ti-6Al-4V	NA	Titanium Alloy	Ti-6Al-4V
Abutment Screw	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	NA	Titanium Alloy	Ti-6Al-4V

The subject device and predicate devices are substantially equivalent in intended use. Minor differences in language in the Indications for Use Statement between the subject device and the predicate devices do not change the intended use of implant placement and function. All are implant systems placed in the maxilla or mandible for single or multi-unit restorations with possible immediate loading. Delayed loading for implants shorter than 7 mm is substantially equivalent to the statement in K120414 limiting immediate loading to implants 8 mm or greater.

Indications for Use Statements of the above predicates, K101225, K120414, and K081653 include an indication for immediate loading. The phrase, “Restorations supported by two or more Sistema de Implante Nacional implants may be loaded immediately after implant placement if primary implant stability has been achieved” in the primary predicate submission, K051859, has been replaced with the phrase, “S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading” as seen for the reference predicate K101225. The phrase, crowns, bridges and overdentures has been replaced with the equivalent statement, “single-unit or multi-unit restorations.” Minor changes in language to the Indications for Use Statement do not affect the safety, efficacy or substantial equivalence of the subject device.

Subject device implants are substantially equivalent to K051859 implants in body, connection design, material and acid-etched surface. The subject device implant HA surface is substantially equivalent to the K101225 surface treatment. The short implant is substantially equivalent to K092035 in size, surface area and function. Subject device abutments are substantially equivalent to K051859 and K120414 abutments in material, design and function. Subject device multi-unit abutments are substantially equivalent to K072570 abutments in material, design and function.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter, length and angle of the abutments. The subject and predicate devices are packaged in similar materials and are to be sterilized using similar methods.

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