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

July 17, 2024

Re: K240609
Trade/Device Name: S.I.N. Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Product Code: DZE, NHA
Dated: March 4, 2024
Received: June 20, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240609

Device Name

S.I.N. Dental Implant System

Indications for Use *(Describe)*

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 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
K240609
S.I.N. - Sistema de Implante Nacional S.A.
S.I.N Dental Implant System

July 17, 2024

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
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code	DZE
Secondary 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
K231127, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.

Reference Devices
K161598, NobelZygoma 0°, Nobel Biocare AB

K190718, Zygomatic Implants, JJGC Indústria e Comércio de Materiais Dentários S.A.
K203542, Neodent Implant System - Mini Abutment 60°, JJGC Indústria e Comércio de Materiais Dentários S.A.

INDICATIONS FOR USE STATEMENT

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 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. This submission includes zygomatic dental implants and mating abutments for screw-retained, multi-unit prostheses.

The subject device Zygomatic Plus Morse Taper implants have a body diameter of 4.0 mm that tapers to approximately 2.3 mm at the apex. The implants have a Morse taper ("CM") abutment interface connection, with an internal 16° cone taper. The abutment platform is 4.0 mm. All implants are threaded starting at the apex and extending approximately 17 mm in the coronal direction, with a major thread diameter of 4 mm; the thread tapers over the final 6 mm of the implant to the apex. The implants are provided with overall lengths of 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, and 60 mm. The surface of all subject device implants is acid-etched from the implant platform to the apex, followed by application of a hydroxyapatite coating (HA^{nano}).

The subject device abutments are multi-unit, indexed abutments for use only with the subject device Zygomatic Plus Morse Taper implants for maxillary full-arch restorations. The subject device abutments have a prosthetic platform diameter of 4.8 mm, and gingival heights of 1.5, 2.0, and 2.5 mm. The prosthetic post is angled 52° or 60° to the long axis of the implant. These components are used with previously cleared abutment screws.

All subject device dental implants are manufactured from unalloyed titanium conforming to ASTM F67. All implants have an acid-etched HA^{nano} surface treatment, identical to that cleared in K231127. All subject device abutments are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136. All subject device implants and abutments are provided sterile to the end user.

PERFORMANCE DATA

Non-clinical data provided in this submission in support of substantial equivalence included:

- mechanical testing conducted using a method modified from ISO 14801 and engineering analysis to demonstrate that the subject device implants, in combination with the subject device abutments have sufficient strength for the intended use.

Non-clinical data referenced from prior submissions in support of substantial equivalence included:

- referenced from K231127, gamma irradiation sterilization validation for all subject devices to a sterility assurance level of 10^{-6} by selecting and substantiating a 25 kGy dose using method VD_{max}^{25} according to ISO 11137-1 and ISO 11137-2;
- referenced from K231127, bacterial endotoxin testing 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 $\leq$ 20 EU/device;
- referenced from K231127 (provided in K222231), 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);
- referenced from K231127 (provided in K203725), sterile barrier shelf life data; and
- referenced from K231127 (provided in K200992), biocompatibility data for the subject device materials (ASTM F67, ASTM F136), and the implant surface treatment (acid-etched and HA^{nano} 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 primary predicate device and the reference device 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 device.

The primary predicate device K231127 is in support of substantial equivalence of the Indications for Use, implant designs, abutment designs, materials, manufacturing, sterilization, and shelf life. The reference device K161598 is in support of substantial equivalence of the abutment design with an angulation of 60°.

The Indications for Use Statement (IFUS) for the subject device is identical to that of the primary predicate device K231127. The IFUS for the subject device is similar to the IFUS of the reference device K161598, including language referring to placement in the upper jaw arch/zygoma, and language concerning immediate loading.

The subject device zygomatic implants are substantially equivalent to the implants in the primary predicate device K231127 in terms of the Morse taper connection, body diameter, platform diameter, and the range of implant lengths. The subject device zygomatic implants have a more rounded, smoother apex as compared to the zygomatic implants in K231127. The subject device zygomatic implants are manufactured from unalloyed titanium conforming to ASTM F67 that is identical to that used for the implants cleared in the primary predicate device K231127. The subject device implants have an endosseous surface (acid-etched and HA^{nano} coating) that also is identical to that of the primary predicate device K231127.

The subject device abutments are identical to the abutments cleared in the primary predicate device K231127 in terms of the material (Ti-6Al-4V alloy conforming to ASTM F136), anodization, Morse taper connection, implant-abutment platform, and prosthetic platform. The subject device abutments are substantially equivalent to the abutments cleared in the reference device K161598 in terms of the maximum angulation (subject device abutments have angulation of 52° or 60°, and abutments cleared in K161598 have angulation of 45° or 60°).

The subject device implants, implant cover screws, and abutments are provided sterile to the end user by means of gamma irradiation; this is the same sterilization method as used for the primary predicate device K231127. The subject device zygomatic implants are packaged in the same way as the zygomatic implants in the primary predicate device K231127. All subject device components are packaged in a polyethylene terephthalate blister pack with a Tyvek cover and the appropriate label. This is the same packaging used for the primary predicate device K231127.

The risks associated with the subject device abutment designs are mitigated by mechanical testing, including comparison testing to constructs of zygomatic implants and abutments from the reference devices K190718 and K203542, respectively, and an engineering rationale demonstrating that the subject device implants in combination with the subject device angled abutments have sufficient strength for their intended use.

CONCLUSION

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

Table of Substantial Equivalence

	Subject Device	**Predicate Device**	**Reference Device**	**Reference Device**	**Reference Device**
	K240609 **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K231127** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K161598** **NobelZygoma 0°** **Nobel Biocare AB**	**K190718** **Zygomatic Implants** **JJGC Indústria e Comércio de Materiais Dentários S.A.**	**K203542** **Neodent Implant System - Mini Abutment 60°** **JJGC Indústria e Comércio de Materiais Dentários S.A.**
Indications for Use Statement	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 loading when good primary stability is achieved and with appropriate occlusal loading.	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 loading when good primary stability is achieved and with appropriate occlusal loading.	NobelZygoma implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arch to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function. The NobelZygoma Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	Zygomatic Implants are indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Zygomatic Implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Zygomatic Implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	The Mini Conical Abutments are indicated for use with Zygomatic Implants, in cases of severe jaw resorption, in order to restore patient aesthetics and chewing function. It may be used with single-stage or two-stage procedures, for multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.
Reason for Predicate / Reference Devices	**Not applicable**	**Indications for Use Statement; implant design; abutment design; materials; sterilization; shelf life**	**Abutment design, angulation of 60°**	**Implant design;** **used in comparative mechanical testing**	**Abutment design;** **used in comparative mechanical testing**
Product Codes	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla	Functional and esthetic rehabilitation of the edentulous maxilla	Functional and esthetic rehabilitation of the edentulous maxilla	Functional and esthetic rehabilitation of the edentulous maxilla	Functional and esthetic rehabilitation of the edentulous maxilla
Implant Designs					
Implant type	Zygomatic	Zygomatic	Zygomatic	Zygomatic	*Not applicable*
Marketing Name	**Implant Zygomatic Morse Taper Plus**	**Implant Zygomatic Plus Morse Taper**	**NobelZygoma 0°**	**Zygomatic Implants**	*Not applicable*
Prosthetic Interface Connections	Morse taper, 16°	Morse taper, 16°	External hex	Morse taper, 16° (GM, Grand Morse)	Morse taper, 16° (GM, Grand Morse)
Body Diameter	4.0 mm (full length)	4.0 mm (full length)	4.5 mm (coronal), taper to 4.3 mm (middle) to 5.0 mm (apical)	4.0 mm (full length)	*Not applicable*
Platform Diameter	4.0 mm	4.0 mm	4.5 mm	4.0 mm	*Not applicable*
Platform-to-Implant Axis Angle	0° (Platform orthogonal to implant long axis)	0° (Platform orthogonal to implant long axis)	0° (Platform orthogonal to implant long axis)	0° (Platform orthogonal to implant long axis)	*Not applicable*
Lengths	30 mm – 60 mm 2.5 mm increments	30 mm – 60 mm 2.5 mm increments	30 mm – 50 mm	30 mm – 55 mm	*Not applicable*
Thread Diameter and Threaded Length	Thread diameter: 4.0 mm Thread length: 17 mm, starts at apex extends coronally	Thread diameter: 4.0 mm Thread length: 17 mm, starts at apex extends coronally	*Not stated in 510(k) Summary*	*Not stated in 510(k) Summary*	*Not applicable*
Implant Material	Unalloyed titanium, ASTM F67	Unalloyed titanium, ASTM F67	Unalloyed titanium, ASTM F67	Unalloyed titanium, ASTM F67	*Not applicable*
Implant Endosseous Surface	Acid-etched and HA^{nano}	Acid-etched and HA^{nano}	TiUnite	Sand blasted, acid etched (NeoPoros)	*Not applicable*
Abutments					
Abutment designs	**Abutment Mini Angled Morse Taper 52°, 60°** Platform Ø: 4.1 mm Prosthetic Platform Ø: 4.8 mm Gingival Height: 1.5, 2, 2.5 mm Angulation: 52°, 60°	**Abutment Mini Angled Morse Taper 45°** Platform Ø: 4.1 mm Prosthetic Platform Ø: 4.8 mm Gingival Height: 2 mm and 3 mm Angulation: 45°	**NobelZygoma 0° Abutments** Platform: Nobel Ex Hex Regular (RP) Prosthetic Platform: *Not stated in 510(k) Summary* Gingival Height: 6, 8, ,10 mm Angulation: 45°, 60°	**Zygomatic Abutments** Platform: Neodent GM Prosthetic Platform: *Not stated in 510(k) Summary* Gingival Height: 1.5, 2.5 mm Angulation: 45°	**Mini Abutment 60°** Platform: Neodent GM Prosthetic Platform: *Not stated in 510(k) Summary* Gingival Height: 1.5, 2.5 mm Angulation: 60°
Prosthesis Attachment	Screw-retained, multi-unit	Screw-retained, multi-unit	Screw-retained, multi-unit	Screw-retained, multi-unit	Screw-retained, multi-unit
Abutment Material	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, Ti-6Al-4V	Titanium alloy, ASTM F136
Abutment Screw Material	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	*Not stated in 510(k) Summary*	*Not stated in 510(k) Summary*

	Subject Device	**Predicate Device**	**Reference Device**	**Reference Device**	**Reference Device**
	K240609 **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K231127** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K161598** **NobelZygoma 0°** **Nobel Biocare AB**	**K190718** **Zygomatic Implants** **JJGC Indústria e Comércio de Materiais Dentários S.A.**	**K203542** **Neodent Implant System - Mini Abutment 60°** **JJGC Indústria e Comércio de Materiais Dentários S.A.**
How Provided					
Implants, Implant Cover Screw	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	*Not applicable*
Abutments	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by ethylene oxide	All sterile by ethylene oxide
Abutment Screws	All sterile by gamma irradiation (Screws were previously cleared)	All sterile by gamma irradiation	All sterile by gamma irradiation	*Not stated in 510(k) Summary*	*Not stated in 510(k) Summary*