



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

December 7, 2023

Re: K231127
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 9, 2023
Received: November 9, 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 (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

Indications for Use

510(k) Number (if known)
K231127

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
K231127
S.I.N. - Sistema de Implante Nacional S.A.
S.I.N Dental Implant System
December 4, 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 872.3640
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
K203725, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.

Reference Devices
K161598, NobelZygoma 0°, Nobel Biocare AB

K222497, ZAGA Zygomatic System, Southern Implants (Pty) Ltd
K190718, Zygomatic Implants, JJGC Indústria e Comércio de Materiais Dentários SA
K200992, 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 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, mating abutments for screw-retained, multi-unit prostheses, and the corresponding abutment screws.

The subject device Zygomatic Plus Morse Taper implants have a body diameter of 4.0 mm that tapers to 1.65 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 2 mm and 3 mm. The prosthetic post is angled 45° to the long axis of the implant. These components are used with subject device abutment and prosthetic screws, or previously cleared 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 K200992. All subject device abutments are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136. All subject device implants, abutments, and abutment screws are provided sterile to the end user.

PERFORMANCE DATA

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

- 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 VDMAX25 according to ISO 11137-1 and ISO 11137-2; and
- mechanical testing conducted using a method modified from ISO 14801 and engineering analysis to demonstrate that the subject device abutments, 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 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 K203725, sterile barrier shelf life data; and
- referenced from 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 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 K203725 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 implant design including the platform 90° to long axis of the implant, the surface-treated unthreaded length of the implant (threads start at apex and extend 18 mm coronally), and the use of the implants with abutments with an angulation of 45°. The reference device K222497 is in support of substantial equivalence of the implant lengths of 30 mm to 60 mm. The reference device K190718 is in support of substantial equivalence of the implant body diameter of 4 mm, implant platform diameter of 4.0 mm, and the use of the implants with abutments with an angulation of 45°. The reference device K200992 is in support of substantial equivalence of the implant endosseous surface treatment (acid-etched and HA^{nano} coating), and the subject device abutment designs.

The Indications for Use Statement (IFUS) for the subject device is identical to the zygomatic implant portion of the IFUS for the primary predicate device K203725. The IFUS for the primary predicate device K203725 includes language for conventional dental implants that is not applicable to the subject device.

The IFUS for the subject device is similar to the IFUS of the reference devices K161598, K222497, and K190718. The IFUS of these reference devices all refer to placement in the upper jaw arch/zygoma, and all include language concerning immediate loading. The slight differences in language for the subject device IFUS compared to these reference devices do not impact the intended use as zygomatic implants. The IFUS for the reference device K200992 is for conventional implants and is not applicable to the subject device. As stated above, the IFUS of the subject device is identical to the zygomatic implant portion of the IFUS for the primary predicate device K203725.

The subject device zygomatic implants are substantially equivalent to the reference devices in terms of the body diameter and platform diameter (K190718), the range of implant lengths (K222497), and the use of the implants with abutments having an angulation of 45° (K161598 and K190718). The subject device zygomatic implant surface (acid-etched and HA^{nano} coating) is identical to that of the reference device K200992. The subject device abutments are substantially equivalent to abutments cleared in the reference device

K200992. The subject device abutments have the same Morse taper interface (16°), prosthetic platform diameter (4.8 mm), and gingival heights (2 mm and 3 mm) as abutments cleared in the reference device K200992. The subject device abutments have a larger angulation (45°) than the abutments cleared in K200992. The risks associated with the subject device abutment designs are mitigated by mechanical testing using a method modified from ISO 14801 and an engineering rationale to demonstrate that the subject device implants in combination with the subject device angled abutments have sufficient strength for their intended use.

The subject device implants, abutments, and abutment screws 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 K203725 and the reference device K200992. The subject device zygomatic implants are packaged in the same way as the zygomatic implants in the primary predicate device K203725. 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 K203725 and the reference device K200992.

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	Reference Device	Reference Device	Reference Device	Reference Device
	K231127 S.I.N. Dental Implant System	K203725 S.I.N. Dental Implant System	K161598 NobelZygoma 0°	K222497 ZAGA Zygomatic System	K190718 Zygomatic Implants	K200992 S.I.N. Dental Implant System
	S.I.N. - Sistema de Implante Nacional S.A.	S.I.N. - Sistema de Implante Nacional S.A.	Nobel Biocare AB	Southern Implants (Pty) Ltd	JJGC Indústria e Comércio de Materiais Dentários SA	S.I.N. - Sistema de Implante Nacional 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 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 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.	Southern Implants ZAGA Zygomatic System implants are intended to be implanted in the upper jaw arch to provide support for fixed dental prostheses in patients with partially or fully edentulous maxillae. All 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.	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.
Reason for Predicate / Reference Devices	Not applicable	Indications for Use Statement; implant design; abutment design; materials; sterilization; shelf life	Implant design; abutment design	Implant design	Implant design	Abutment design; implant HA ^{nano} surface
Product Codes	DZE, NHA	DZE, NHA	DZE, NHA	DZE	DZE, NHA	DZE, NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla	Functional and esthetic rehabilitation of the edentulous mandible or 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 mandible or maxilla
Implant Designs						
Implant type	Zygomatic	Zygomatic	Zygomatic	Zygomatic	Zygomatic	Conventional
Prosthetic Interface Connections	Morse taper, 16°	External hex	External hex	External hex	Morse taper (GM, 16°)	Morse taper, 11.5°
Body Diameter	4.0 mm (full length)	4.5 mm (coronal) taper to 3.85 mm (apical)	4.5 mm (coronal), taper to 4.3 mm (middle) to 5.0 mm (apical)	ZAGA round: 4.3 mm (coronal) taper to 3.4 mm (apical) ZAFA flat: 4.3 mm (coronal with 3.35 mm flat) taper to 3.4 mm (apical)	4.0 mm (full length)	Various implant body/platform diameters 3.5/3.5 mm to 5.0/5.0 mm
Platform Diameter	4.0 mm	4.1 mm	4.5 mm	4.07 mm	4.0 mm	

	Subject Device	Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device
	K231127 S.I.N. Dental Implant System	K203725 S.I.N. Dental Implant System	K161598 NobelZygoma 0°	K222497 ZAGA Zygomatic System	K190718 Zygomatic Implants	K200992 S.I.N. Dental Implant System
	S.I.N. - Sistema de Implante Nacional S.A.	S.I.N. - Sistema de Implante Nacional S.A.	Nobel Biocare AB	Southern Implants (Pty) Ltd	JJGC Indústria e Comércio de Materiais Dentários SA	S.I.N. - Sistema de Implante Nacional S.A.
Platform-to-Implant Axis Angle	0° (Platform 90° to implant long axis)	45°	0° (Platform 90° to implant long axis)	55°	0° (Platform 90° to implant long axis)	0° (Platform 90° to implant long axis)
Lengths	30 mm – 60 mm 2.5 mm increments	34 mm – 59 mm	30 mm – 50 mm	ZAGA Round: 30, 32.5, 57.5, 60 mm ZAGA Flat: 55, 57.5, 60 mm	30 mm – 55 mm	8.5 mm – 15 mm
Thread Diameter and Threaded Length	Thread diameter: 4.0 mm Thread length: 17 mm, starts at apex extends coronally	Coronal thread diameter: 4.5 mm Coronal threaded length: 2.15 mm Apical thread diameter: 3.85 mm Apical thread length: 10.7 mm	Thread diameter: <i>not stated in 510(k) Summary</i> Thread length: <i>18 mm, starts at apex extends coronally</i>	<i>Not stated in 510(k) Summary</i>	<i>Not stated in 510(k) Summary</i>	Various thread diameters; All implants fully threaded
Implant Material	Unalloyed titanium, ASTM F67	Unalloyed titanium, ASTM F67	Unalloyed titanium, ASTM F67	Unalloyed titanium, ASTM F67	Unalloyed titanium, ASTM F67	Unalloyed titanium, ASTM F67
Implant Endosseous Surface	Acid-etched and HA ^{nano}	Acid-etched	TiUnite	Grit-blasted	NeoPoros (Grit-blasted and acid-etched)	Acid-etched only and Acid-etched and HA ^{nano}
Abutments						
Abutment designs	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°	Mini Abutment Zygomatic Standard Platform Ø: 4.1 mm Prosthetic Platform Ø: 4.5 mm Gingival Heights: 3, 4, 5.5 mm Angulation: 0° (straight)	NobelZygoma 0° Abutments Platform: Nobel Ex Hex Regular (RP) Prosthetic Platform: <i>Not stated in 510(k) Summary</i> Gingival Height: 6, 8, ,10 mm Angulation: 45°, 60°		45° angled abutments made of titanium alloy, intended exclusively for use with the GM Zygomatic implants	Various designs including: Abutment Mini Angled Morse Morse taper interface 16° Prosthetic platform Ø: 4.8 mm Gingival height: 2, 3, 4 mm Angulation: 17°, 30°
		Mini Abutment Zygomatic Conical Platform Ø: 4.1 mm Prosthetic Platform Ø: 4.8 mm Gingival heights: 2, 3, 4 mm Straight				
Prosthesis Attachment	Screw-retained, multi-unit	Screw-retained, multi-unit	Screw-retained, multi-unit	Screw-retained, multi-unit	Screw-retained, multi-unit	Screw-retained, multi-unit Cement-retained single-unit
Abutment Material	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	<i>Not stated in 510(k) Summary</i>	Titanium alloy	Titanium alloy, ASTM F136
Abutment Screw Material	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	<i>Not stated in 510(k) Summary</i>	<i>Not stated in 510(k) Summary</i>	Titanium alloy, ASTM F136
How Provided						
Implants	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation
Abutments, Implant Cover	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	<i>Not applicable (not in submission)</i>	All sterile by ethylene oxide exposure	All sterile by gamma irradiation
Abutment Screws	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	<i>Not applicable (not in submission)</i>	<i>Not stated in 510(k) Summary</i>	All sterile by gamma irradiation