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

June 23, 2021

Re: K203725
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: March 30, 2021
Received: March 31, 2021

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
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)*

K203725

Device Name

S.I.N. Dental Implant System

Indications for Use *(Describe)*

For Strong SW HE 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.
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.

For Zygomatic Implants and Abutments

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.

510(k) Summary
K203725
S.I.N. - Sistema de Implante Nacional S.A.
S.I.N Dental Implant System

June 23, 2021

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
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 Health Technology 1 B (Dental Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K170398, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.

Reference Devices
K160119, NobelSpeedy® Groovy, Nobel Biocare AB
K173343, Zygomatic Implant System, Southern Implants (Pty) Ltd

INDICATIONS FOR USE STATEMENTS

For Strong SW HE 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.
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.

For Zygomatic Implants and Abutments

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 cleared in K170398, including a line of zygomatic dental implants and abutments.

The subject device Strong SW HE dental implants are nearly identical to the Strong SW HE dental implants cleared in K170398, with a cylindrical design that tapers slightly to the apex, a body/endosseous thread diameter of 3.75 mm, and a platform diameter of 4.1 mm. This submission adds overall lengths of 18, 20, 22, and 24 mm. The endosseous threads have a uniform trapezoidal design and have an acid-etched surface. The implants have an external hexagon (“HE”) abutment interface connection, internal threads, and an internal hexolobular feature for instrument attachment.

The subject device Zygomatic dental implants have a body diameter of 4.5 mm at the coronal end and a body diameter of 3.85 mm at the apical end with additional tapering to the apex. The abutment platform is 4.1 mm and is angled 45° to the long axis of the implant. The coronal end of the Zygomatic implants have a micro-channel surface feature starting at approximately the middle of the angled abutment platform extending over a length of approximately 2.9 mm; the micro-channel blends to a micro-thread and extends apically over a length of 2.15 mm. The micro-thread major diameter is 4.5 mm. All Zygomatic implants also are threaded over a length of 10.7 mm at the apical end with a major thread diameter of 3.85 mm. The endosseous threads at the apical aspect of the Zygomatic implants have the same uniform trapezoidal design and acid-etched surface as the Strong SW HE implants. The implants are provided in a range of lengths from 34 mm to 59 mm in 2.5 mm increments. The implant length is measured from the start of the micro-threads to the apex.

This submission includes an implant cover for the subject Zygomatic implants, with a coronal diameter of 4.1 mm that matches the implant platform, and is threaded to match the internal thread of the Zygomatic implants. This submission also includes Mini Abutment Zygomatic Standard and Mini Abutment Zygomatic Conical; these abutments are straight, multi-unit, non-indexed abutments for the external hex connection of the Zygomatic implants. Mini Abutment Zygomatic Standard and Mini Abutment Zygomatic Conical are straight, multi-unit, non-indexed abutments for the external hex connection of the

Zygomatic implants. Mini Abutment Zygomatic Standard are provided in one platform diameter (4.1 mm), one prosthetic platform diameter (4.5 mm), and in gingival heights of 3 mm, 4 mm, and 5.5 mm. Mini Abutment Zygomatic Conical are provided in one platform diameter (4.1 mm), one prosthetic platform diameter (4.8 mm), and in gingival heights of 2 mm, 3 mm, and 4 mm. Each abutment requires a corresponding subject device abutment screw to match the gingival height of the abutment. The Mini Abutment Standard and Mini Abutment Conical are the only abutments that are compatible with the subject device Zygomatic implants. For the Mini Abutment Zygomatic Standard, this submission also includes an Abutment Protector and a castable Co-Cr Base. For the Mini Abutment Zygomatic Conical, this submission also includes an Abutment Protector, Temporary Titanium Cylinder, and a castable Co-Cr Base. A Coping Screw is also included for use with all zygomatic abutments.

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

Implant Line	Body Ø, mm	Platform Ø, mm	Lengths, mm
Strong SW HE	3.75	4.1	18, 20, 22, 24
Zygomatic	4.5 coronal 3.85 apical	4.1	34, 36.5, 39, 41.5, 44, 46.5, 49, 51.5, 54, 56.5, 59

All subject device dental implants are manufactured from unalloyed titanium conforming to ASTM F67. The subject device abutments, abutment screws, and implant cover are manufactured from titanium alloy conforming to ASTM F136. The materials in this submission (conforming to ASTM F67 and ASTM F136) are identical to the materials used to manufacture the dental implants and abutments cleared in K170398. 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 K170398.

The subject device Mini Abutment Zygomatic Standard and Mini Abutment Zygomatic Conical abutments and corresponding abutment screws manufactured from titanium alloy (ASTM F136) are anodized using standard electrolytic passivation processing to increase the thickness of the natural oxide layer on the surface and to impart a distinctive gold surface color. The anodization process used in this submission is identical to the anodization process used on abutments cleared in K170398. The Abutment Protectors and Coping Screw are manufactured from titanium alloy (ASTM F136), the Co-Cr Bases are manufactured from Co-Cr-Mo alloy (ASTM F1537), and the Temporary Titanium Cylinder is manufactured from unalloyed titanium (ASMT F67).

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 K170398);

bacterial endotoxin testing (referenced from K170398) 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 K170398) 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;

biocompatibility data on subject device materials and manufacturing processes (including the acid-etching surface treatment for dental implants and anodization for abutment and abutment screws) leveraged from K170398;

and static compression and compression fatigue testing of worst-case constructs comprising the subject device Zygomatic implants and compatible subject device Mini Abutment Zygomatic Standard in conformance with ISO 14801 and the zygomatic implant placement protocol for nominal bone level.

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 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 Indications for Use Statement (IFUS) for the subject device consists of two parts: the first is for the addition of longer lengths of conventional implants to those cleared in the primary predicate K170398, and the second part for the subject device zygomatic implants.

The subject device IFUS for conventional implants is substantially equivalent to that of the primary predicate K170398, with differences in language regarding the longer subject device implant lengths. The primary predicate K170398 IFUS includes language regarding shorter implant lengths that is not applicable to the subject device. The language in the subject device IFUS concerning the longer length implants is substantially equivalent to similar language in the reference device K160119.

The IFUS for the subject device, K1709398, and K160119 all contain similar language regarding placement in the mandibular and maxillary arches, single-unit and multi-unit restorations, and immediate loading. Differences between the IFUS of the subject device and the reference device K160119 include slight differences in descriptions of loading protocols, details of implant placement, and the specific names of the devices. These differences in the language of the Indications for Use statements do not affect the intended use as an endosseous dental implant for support of a prosthesis to restore chewing function.

The subject device IFUS for zygomatic implants is substantially equivalent to that of the reference device K173343. Differences between the IFUS for the subject device zygomatic implants and the reference device K173343 include differences in the specific device names and slight differences in the exact wording, including “intended for placement” versus “intended to be implanted.” These differences in the language of the Indications for Use statements do not affect the intended use as an endosseous dental implant for support of a prosthesis to restore chewing function.

None of these minor differences in specific wording among the IFUS impact substantial equivalence. All IFUS express equivalent intended use to facilitate functional and esthetic rehabilitation of the edentulous

mandible or maxilla, and the indications are expressed equivalently using different specific wording.
Subject Device Strong SW HE Implants

The subject device Strong SW HE implants have an identical design, other than the implant lengths, to the Strong SW HE implants cleared in K170398. The subject device Strong SW HE implants have an external hex abutment connection, a body/endosseous thread major diameter of 3.75 mm, and a platform diameter of 4.1 mm, the same as implants cleared in K170398. The subject device Strong SW HE implant lengths are substantially equivalent to the lengths of the implants in predicate device K160119. The subject device Strong SW HE implants are manufactured from unalloyed titanium conforming to ASTM F67 and the endosseous threaded surface is acid etched. The unalloyed titanium material and acid etching used for the subject device implants are identical to that used to manufacture the Strong SW HE dental implants cleared in K170398. The subject device Strong SW HE implants are compatible with previously cleared S.I.N. - Sistema de Implante Nacional S.A. abutments and other components.

Subject Device Zygomatic Implants, Implant Cover, and Abutments

The subject device Zygomatic implants are substantially equivalent in design and material to the Zygan implants from Southern Implants cleared in K173343. The subject device Zygomatic implants and the Zygan implants both have a tapered, partially threaded design with similar coronal and apical threaded diameters, and both have angled external hex abutment platforms. Both implants are manufactured from unalloyed titanium conforming to ASTM F67. The threads of the subject device Zygomatic implants threads receive the same acid etching used for the subject device Strong SW HE implants, and is identical to acid etching used to manufacture the Strong SW HE dental implants cleared in K170398. The Zygan implants cleared in K173343 have an aluminum oxide blasted surface. Both acid etching and grit blasting are surface treatments to increase surface roughness; the subject zygomatic implants are otherwise substantially equivalent to the K173343 zygomatic implants. The difference in the method used to increase surface roughness does not affect substantial equivalence.

The subject device Zygomatic implants are provided in threaded lengths of 34 mm to 59 mm, with the length measured from the start of the micro-threads (at the coronal end) to the apex (tip). The Zygan implants cleared in K173343 are provided in lengths of 30 mm to 57.5 mm, with the length measured from the start of the coronal threads (below the base of the angled platform) to the apex (tip); this length is measured the same length in the same manner as the subject device. Additional length concerns in the subject device have been addressed and are supported by labeling mitigations for implant placement and matched surgical protocol for bone contact, as demonstrated by dynamic fatigue testing in conformance with ISO 14801.

The risks associated with the angled connection (platform angled 45° to the long axis of the implant) between the zygomatic implant and the compatible straight abutments was mitigated by mechanical testing performed in conformance with ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants.* Based on results of dynamic testing in conformance with ISO 14801 and the zygomatic implant placement protocol for nominal bone level, the subject device zygomatic implants were shown to have sufficient strength for their intended use.

The subject device Zygomatic Implant Cover is substantially equivalent in design, material, and size to implant covers for the Strong SW HE external hex connection implants cleared in K170398.

Similarly, the subject device Mini Abutment Zygomatic Standard and Mini Abutment Zygomatic Conical are substantially equivalent in design, material, and sizes to Mini Abutments and Conical Abutments for S.I.N. (Sistema de Implante Nacional S.A.) external hex connection implants cleared in K170398, including the ranges of platform diameters, prosthetic platform diameters, and gingival heights. The primary predicate device K170398 includes Mini Abutments and Conical Abutments with the same designs for screw-retained, multi-unit prostheses. The subject device Mini Abutment Zygomatic Standard and Mini Abutment Zygomatic Conical are substantially equivalent in design, material, and sizes to zygomatic abutments in the predicate device K173343.

The subject Abutment Protectors, castable Co-Cr Bases, Temporary Titanium Cylinder, and Coping Screw are identical in design, material, and sizes to these components cleared for use with conventional dental implants in K193096, K170398, and K051859.

Minor differences in the exact dimensions of the subject device components as compared to those of the primary predicate device and reference devices do not impact safety, effectiveness, or substantial equivalence.

All subject device components are provided sterile by gamma irradiation, the same sterilization method used in K170398.

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 predicate devices listed above.

Table of Substantial Equivalence

	Subject Device	**Primary Predicate**	**Reference Device**	**Reference Device**
	S.I.N. Dental Implant System **S.I.N. - Sistema de Implante Nacional S.A.**	**K170398** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K160119** **NobelSpeedy® Groovy** **Nobel Biocare AB**	**K173343** **Zygomatic Implant System** **Southern Implants (Pty) Ltd**
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 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. Revolution Compact with a 6 mm length is intended for delayed loading only.	NobelSpeedy® Groovy implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelSpeedy® Groovy implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants allow also for bi-cortical anchorage in cases of reduced bone density. NobelSpeedy® Groovy implants 20, 22, 25 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.	Southern Implants Zygomatic System Standard implants, Zygan (narrow apex) implants, and Oncology implants are intended to be implanted in the upper jaw arch to provide support for fixed or removable 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.
Reason for Predicate / Reference Devices	**Not applicable**	**Implant designs; abutment designs; materials; sterilization; shelf life**	**Standard implant designs (lengths)**	**Zygomatic implant designs (Zygan implant)**
Product Codes	DZE, NHA	DZE, NHA	DZE	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 maxilla
Standard Implant Designs				
	Strong SW HE Implants	**Strong SW HE Implants**		
Prosthetic Interface Connections	External hex (HE)	External hex (HE)	External hex	
Body/Platform Diameter, mm	3.75/4.1	3.5/3.65, 3.75/4.1, 4.0/4.1, 4.5/4.5, 5.0/5.0	4.0/RP (4.1)	
Lengths, mm	18, 20, 22, 24	7, 8.5, 10, 11.5, 13, 15 **no 7 mm for 4.5/4.5 diameter*	20, 22, 25	
Implant Material	Unalloyed titanium, ASTM F67	Unalloyed titanium, ASTM F67	CP titanium	
Implant Endosseous Surface	Acid-etched	Acid-etched	TiUnite	
Zygomatic Implant Designs				
Prosthetic Interface Connections	External hex (HE)			External hex
Body Diameter Coronal aspect Apical aspect	 4.5 mm 3.85 mm			Zygan Implant 4.3 mm 3.4 mm
Platform Diameter	4.1 mm			4.05 mm
Platform-Implant Axis Angle	45°			55°
Lengths	34 mm – 59 mm			30 mm – 57.5 mm
Thread Diameter and Threaded Length	Coronal thread diameter: 4.5 mm Coronal threaded length: 2.15 mm Apical thread diameter: 3.85 mm Apical thread length: 10.7 mm			Coronal thread diameter: 4.3 mm Coronal threaded length: *Not in 510(k) Summary* Apical thread diameter: 3.4 mm Apical thread length: 15 mm
Implant Material	Unalloyed titanium, ASTM F67			Unalloyed titanium, ASTM F67
Implant Endosseous Surface	Acid-etched			Aluminum oxide grit blasted

	Subject Device	Primary Predicate	Reference Device	Reference Device
	S.I.N. Dental Implant System **S.I.N. - Sistema de Implante Nacional S.A.**	**K170398** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K160119** **NobelSpeedy® Groovy** **Nobel Biocare AB**	**K173343** **Zygomatic Implant System** **Southern Implants (Pty) Ltd**
Abutment Designs – Zygomatic Implants				
Implant Cover	Implant Cover for Zygomatic Implant Coronal diameter 4.1 mm	Implant Cover for Strong SW HE Implant Coronal diameters: 3.5, 4.1, 5.0 mm		*Not stated in 510(k) Summary*
Abutment Components	Mini Abutment Zygomatic Standard Platform Ø: 4.1 mm Prosthetic Platform Ø: 4.5 mm Gingival heights: 3, 4, 5.5 mm Straight	Mini Abutment Platform Ø: 3.6 mm Prosthetic Platform Ø: 4.8 mm Gingival heights: 1, 2, 3, 4 mm Straight		Compact Conical Abutments Platform Ø: *not in 510(k) Summary* Prosthetic Platform Ø: *not in 510(k) Summary* Gingival height: 2, 3, 4, 5.5 mm Straight
	Mini Abutment Zygomatic Conical Platform Ø: 4.1 mm Prosthetic Platform Ø: 4.8 mm Gingival heights: 2, 3, 4 mm Straight	Conical Abutment Platform Ø: 3.6 mm Prosthetic Platform Ø: 4.8 mm Gingival heights: 1, 2, 3, 4 mm Straight		Titanium Cylinder Abutment (Coping for Compact Conical Abutments) Gingival height 5 mm
	Abutment Protector, Ø 5 mm	Abutment Protector, Ø 5 mm		
	Co-Cr Base (castable), Ø 4.5 and Ø 5 mm			
	Temporary Titanium Sleeve , Ø 4.8 mm (for Mini Abutment Zygomatic Conical)			Titanium Cylinder Abutment, prosthetic platform Ø 3.4 mm
	Coping Screw, Ø 2.3 x 4.4 mm			
Prosthesis Attachment	Screw-retained, multi-unit	Screw-retained, multi-unit		Screw-retained, multi-unit
Abutment Component Materials	Titanium alloy, ASTM F136: abutments, implant cover, abutment protectors Unalloyed titanium ASTM F67: titanium cylinder Co-Cr-Mo alloy, ASTM F1537: Co-Cr bases	Titanium alloy, ASTM F136		Unalloyed titanium, ASTM F67; Titanium alloy, ASTM F136
Abutment Screws Material	Titanium alloy, ASTM F136: abutment screws and coping screw	Titanium alloy, ASTM F136		*Not stated in 510(k) Summary*
Implants	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	Sterile, *method not stated in 510(k) Summary*
Abutments, Implant Cover	All sterile by gamma irradiation	All sterile by gamma irradiation	*Not applicable (not in submission)*	*Not stated in 510(k) Summary*
Abutment Screws	All sterile by gamma irradiation	All sterile by gamma irradiation	*Not applicable (not in submission)*	*Not stated in 510(k) Summary*