November 17, 2020

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

Re: K200992
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: October 16, 2020
Received: October 16, 2020

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200992

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.

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
K200992
S.I.N. - Sistema de Implante Nacional S.A.
S.I.N Dental Implant System

November 17, 2020

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

Additional Predicate Devices
K170398, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.
K163194, Neodent Implant System - GM Line, JJGC Indústria e Comércio de Materiais Dentários SA
K101945, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA

K961736, 17° Angulated Abutment, Nobel Biocare USA, LLC
K905434, Angulated Abutment, Complete, Titanium SDCA 102, Nobelpharma USA, Inc.
K161416, Multi-unit Abutment Plus, Nobel Biocare AB
K052600, Zimmer Dental Incorporated, Zimmer Dental Hex-lock Prepared Abutment (Straight & Angled)
K110955, MegaGen Company, Limited, AnyRidge Internal Implant System

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.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to add to the S.I.N. Dental Implant System components cleared in K170392 and K170398. This submission adds the following components to the S.I.N. Dental Implant System:

Tryon CM Conical implants, Tryon CM Cylindrical implants, Tryon CM Cylindrical Body and Conical Apex implants, and Strong SW implants, each with a Morse taper connection and the identical acid-etched endosseous surface cleared in in K170392;

Strong SW Plus implants with a Morse taper connection and an endosseous surface produced by acid-etching followed by application of a hydroxyapatite coating (HA^{nano}) identical to the coating cleared in K170392;

conventional angled abutments and healing caps with a Morse taper connection that are compatible with the Strong SW CM implant line cleared in K170392;

conventional angled abutments and healing caps with a Morse taper connection that are compatible with the subject device Tryon CM implant lines, the subject device Strong SW/Plus implant lines, and the Unitite implant line cleared in K17039;

healing caps with a Morse taper connection that are compatible with the Unitite Compact implant line and the Unitite Slim implant line cleared in K170392;

healing caps with an external hex (HE) or internal hex (HI) connection that are compatible with the Strong SW HE, the Tryon HE implant lines, and the Strong SW HI implant lines, cleared in K170398;

abutment screws for use with the angled abutments or healing caps.

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

Implant Line	Body Ø, mm	Platform Ø, mm	Length, mm					
Tryon CM Conical	3.5	3.5		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
Tryon CM Cylindrical	3.5	3.5	7	8.5	10	11.5	13	15
	3.75	3.75	7	8.5	10	11.5	13	15
	4.0	4.0	7	8.5	10	11.5	13	15
	5.0	5.0	7	8.5	10	11.5	13	15

Implant Line	Body Ø, mm	Platform Ø, mm	Length, mm					
Tryon CM Cylindrical Body and Conical Apex	3.5	3.5		8.5	10	11.5	13	15
	3.75	3.75		8.5	10	11.5	13	15
	4.0	4.0		8.5	10	11.5	13	15
Strong SW	3.5	3.5		8.5	10	11.5	13	15
	3.8	3.8		8.5	10	11.5	13	15
Strong SW Plus	4.5	4.5		8.5	10	11.5	13	15
	5.0	5.0		8.5	10	11.5	13	15

All subject device dental implants are made of the same unalloyed titanium as the dental implants cleared in K170398 and K170392, and the Strong SW Plus implants have the identical HA^{nano} surface cleared in K170392.

Prosthetic Components

The subject device prosthetic components are summarized in the following table.

Types	Prosthetic Platform Ø, mm	Angle	Materials	Compatible with
Abutment Cemented Morse Angled (16° Morse taper)	3.3, 4.5	17°, 30°	Titanium alloy	Strong SW CM implant line in K170392
Abutment Angled Morse (16° Morse taper)	3.5, 4.5	17°	Titanium alloy	
Abutment Mini Angled Morse (16° Morse taper)	4.8	17°, 30°	Titanium alloy	
Healing Cap Morse (16° Morse taper)	n/a	n/a	PEEK	
Healing Cap Morse Indexed (16° Morse taper)	n/a	n/a	PEEK	
Abutment Cemented Angled SIT (11.5° Morse taper)	3.3, 4.5	17°, 30°	Titanium alloy	Tryon CM implant lines, Strong SW, Strong SW Plus (this submission); Unitite implant line in K170392
Abutment Cemented Angled Indexed SIT (11.5° Morse taper)	3.3, 4.5	17°, 30°	Titanium alloy	
Abutment Mini Angled (11.5° Morse taper)	4.8	17°, 30°	Titanium alloy	
Healing Cap (11.5° Morse taper)	n/a	n/a	PEEK	
Healing Cap Indexed (11.5° Morse taper)	n/a	n/a	PEEK	
Healing Cap Compact (4° Morse taper)	n/a	n/a	PEEK	Unitite Compact implant line in K170392
Healing Cap Compact Indexed (4° Morse taper)	n/a	n/a	PEEK	
Healing Cap Slim (3° Morse taper)	n/a	n/a	PEEK	Unitite Slim implant line in K170392
Healing Cap Slim Indexed (3° Morse taper)	n/a	n/a	PEEK	
Healing Cap HE	n/a	n/a	PEEK	Strong SW HE and Tryon HE implant lines in K170398
Healing Cap HE Indexed	n/a	n/a	PEEK	
Healing Cap HI	n/a	n/a	PEEK	Strong SW HI implant line in K170398
Healing Cap HI Indexed	n/a	n/a	PEEK	

All subject device prosthetic components are manufactured from the same titanium alloy material conforming to ASTM F136 used to manufacture similar components abutments cleared in K170392 and K170398, or from polyetheretherketone (PEEK) conforming to ASTM F2026.

PERFORMANCE DATA

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

gamma irradiation sterilization validated for all subject devices (dental implants manufactured from unalloyed titanium with the acid-etched surface and implants with the HA^{nano} hydroxyapatite coating, abutments and prosthetic components manufactured from titanium alloy, and healing caps manufactured from PEEK) 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;

bacterial endotoxin testing (referenced from K170398 and K170392) 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;

shelf life testing (referenced from K170398 and K170392) 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 testing for the subject device PEEK material performed according to ISO 10993-5 (cytotoxicity) and ISO 10993-12;

biocompatibility testing for the HA^{nano} hydroxyapatite coating leveraged from and provided in K170392 included ISO 10993-3 (genotoxicity), ISO 10993-5 (cytotoxicity), ISO 10993-6 (implantation), ISO 10993-10 (sensitization, irritation), and ISO 10993-11 (systemic toxicity);

characterization of the HA^{nano} hydroxyapatite coating leveraged from and provided in K170392 included scanning electron microscopy (SEM), x-ray photoelectron spectroscopy (XPS), transmission electron microscopy (TEM), x-ray diffraction (XRD), and testing of the adherence of the coating;

and static compression and compression fatigue testing according to ISO 14801 of worst-case constructs of the subject device abutments and subject device implants with the 11.5° Morse taper connection, and of worst-case constructs of the subject device abutments with the 16° Morse taper connection and previously-cleared compatible implants (cleared in K170392 and K193096).

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 additional predicate 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 selected additional predicate devices.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate K170392 and the additional predicate device K170398; slight differences in language of the Indications for Use statements do not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function.

Minor differences between the IFUS for the subject device and the primary predicate K170392 include the exact wording regarding immediate loading and language concerning implants less than 7 mm in length. The minor differences between the IFUS for the subject device and the additional predicate device

K170398 include the exact wording regarding immediate loading and language concerning the Revolution Compact implant.

Minor differences between the IFUS for the subject device and the additional predicate K163194 include the exact wording regarding immediate loading, language in K163194 concerning titanium base abutments (not applicable to the subject device), and language in K163194 regarding the temporary abutments. Minor differences between the IFUS for the subject device and the additional predicate K101945 include the exact wording regarding immediate loading and splinting of multiple tooth applications.

None of these minor differences impact safety or effectiveness because 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 Dental Implants

The subject device Strong SW and Strong SW Plus implants are similar in design and sizes to the Strong SW CM implants cleared in K170392. The subject device Strong SW and Strong SW Plus implants have an 11.5° Morse taper connection, whereas the Strong SW CM implants have a 16° Morse taper connection. The Unitite implant line also cleared in K170932 have the 11.5° Morse taper connection. The subject device Strong SW Plus implants have the identical HAnano surface cleared in K170392.

The subject device Tryon CM implant lines are substantially equivalent in design and sizes to the Tryon HE implants cleared in K170398. The subject device Tryon CM implant lines have the same 11.5° Morse taper connection as the Unitite implant line cleared in K170932.

The subject device dental implants are made of the same unalloyed titanium as the dental implants cleared in K170392 and K170398, and the identical HAnano surface cleared in K170392 (for the subject device Strong SW Plus implants).

The 1.5 mm sub-crestal placement of the subject device implants is substantially equivalent to the sub-crestal placement of implants cleared in K170398, K163194, and K101945.

Subject Device Prosthetic Components

All subject device conventional abutments are manufactured from the same titanium alloy material conforming to ASTM F136 used to manufacture S.I.N. Dental Implant System abutments cleared in K170392 and K170398, or from polyetheretherketone (PEEK) conforming to ASTM F2026.

The subject device Abutment Cemented Morse Angled and Abutment Angled Morse (with 16° Morse taper) are substantially equivalent to the corresponding abutment design Abutment Cemented Strong SW CM cleared in K170392, having the same sizes or ranges of sizes for prosthetic platform diameter and gingival height. The subject device Abutment Cemented Morse Angled and Abutment Angled Morse are substantially equivalent to the GM Exact Click Universal Abutment cleared in K163194 in terms of prosthetic diameter, indexing, and angulation. The additional predicate devices K05260 and K110955 are in support of substantial equivalence of the Abutment Angled Morse with 17° of angulation and gingival heights of 1 mm, 4 mm, and 5 mm.

The subject device Abutment Mini Angled Morse (with 16° Morse taper) are substantially equivalent to the corresponding abutment design Mini Abutment Strong SW CM cleared in K170392, having the same sizes or ranges of sizes for prosthetic platform diameter and gingival height. The subject device Abutment Mini Angled Morse is substantially equivalent to the GM Mini Conical Abutment cleared in K163194 in terms of prosthetic diameter, indexing, and angulation. The additional predicates K961736, K905434, and K161416 are in support of substantial equivalence of the Abutment Mini Angled Morse with 17° and 30° of angulation and a gingival height of 4 mm.

The subject device Abutment Cemented Angled SIT and Abutment Cemented Angled Indexed SIT (with 11.5° Morse taper) are substantially equivalent to the corresponding abutment design Abutment Cemented SIT Unitite cleared in K170392, having the same sizes or ranges of sizes for prosthetic platform diameter and gingival height. The subject device Abutment Cemented Angled SIT and Abutment Cemented Angled Indexed SIT are substantially equivalent to the CM Universal Abutment cleared in K101945 in terms of indexing and angulation.

The subject device Abutment Mini Angled (with 11.5° Morse taper) are substantially equivalent to the corresponding abutment design Mini Abutment Unitite cleared in K170392, having the same sizes or ranges of sizes for prosthetic platform diameter and gingival height. The subject device Abutment Mini Angled is substantially equivalent to the CM Mini Conical Abutment cleared in K101945 in terms of indexing and angulation.

The subject device Healing Cap Morse and Healing Cap Morse Indexed (with 16° Morse taper) are substantially equivalent to the corresponding design Healing Abutment Strong SW CM cleared in K170392, and to the GM Pro PEEK (Temporary) Abutment cleared in K163194. The GM Pro PEEK (Temporary) Abutment is for support of substantial equivalence of the PEEK material.

The subject device Healing Cap and Healing Cap Indexed (with 11.5° Morse taper) are substantially equivalent to the corresponding design Healing Abutment Unitite cleared in K170392, and to the GM Pro PEEK (Temporary) Abutment cleared in K163194. The GM Pro PEEK (Temporary) Abutment is for support of substantial equivalence of the PEEK material.

The subject device Healing Cap Compact and Healing Cap Compact Indexed (with 4° Morse taper) are substantially equivalent to the corresponding design Healing Abutment Unitite Compact cleared in K170392, and to the GM Pro PEEK (Temporary) Abutment cleared in K163194. The GM Pro PEEK (Temporary) Abutment is for support of substantial equivalence of the PEEK material.

The subject device Healing Cap Slim and Healing Cap Slim (with 3° Morse taper) are substantially equivalent to the corresponding design Healing Abutment Unitite Slim cleared in K170392, and to the GM Pro PEEK (Temporary) Abutment cleared in K163194. The GM Pro PEEK (Temporary) Abutment is for support of substantial equivalence of the PEEK material.

The subject device Healing Cap HE and Healing Cap HE Indexed (external hex interface) are substantially equivalent to the corresponding designs Healing Abutment and Cover Screw with external hex interfaces cleared in K170398, and to the GM Pro PEEK (Temporary) Abutment cleared in K163194. The GM Pro PEEK (Temporary) Abutment is for support of substantial equivalence of the PEEK material. The additional predicate K110955 is in support of substantial equivalence of the Healing Cap HE and Healing Cap HE Indexed with a coronal diameter of 8 mm and a gingival height of 6.8 mm.

The subject device Healing Cap HI and Healing Cap HI Indexed (internal hex interface) are substantially equivalent to the corresponding designs Healing Abutment and Cover Screw with internal hex interfaces cleared in K170398, and to the GM Pro PEEK (Temporary) Abutment cleared in K163194. The GM Pro PEEK (Temporary) Abutment is for support of substantial equivalence of the PEEK material. The additional predicate K110955 also is in support of substantial equivalence of the Healing Cap HI and Healing Cap HI Indexed with a coronal diameter of 8 mm and a gingival height of 6.8 mm.

All subject device healing caps are designed for the healing period between implant placement and final abutment placement, and are not intended to support a temporary prosthesis. The GM Pro PEEK (Temporary) Abutment cleared in K163194 is used to support a provisional prosthesis. This difference does not impact the substantial equivalence of the use of PEEK material for a healing cap or healing abutment.

Minor differences in the exact dimensions of the subject device abutments as compared to the primary predicate and additional predicate devices does not impact safety, effectiveness, or substantial equivalence.

The subject device abutments screws are substantially equivalent in material (titanium alloy) and designs to abutment screws cleared in K170392 and K170398. Selected abutments manufactured from titanium alloy are anodized using a standard anodization process is identical to the anodization process used on abutments cleared in K170392 and K170398.

All subject device components are provided sterile by gamma irradiation, the same sterilization method used in K170392 and K170398.

CONCLUSION

The subject device, the primary predicate device, and the additional predicate 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 additional predicate 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 Device	Additional Predicate	Additional Predicate	Additional Predicate
	K200992 **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K170392** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K170398** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K163194** **Neodent Implant System - GM Line** **JJGC Indústria e Comércio de Materiais Dentários SA**	**K101945** **Neodent Implant System** **JJGC Indústria e Comércio de Materiais Dentários SA**
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 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.	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.	Indications for Use for GM implants and conventional abutments: The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Indications for Use for GM Titanium Base abutments: Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center. Indications for Use for GM Pro Peek Abutments: The Pro PEEK Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted.
Reason for Predicate / Reference Devices	**Not applicable**	**Implant designs; abutment designs; HA^{nano} implant surface**	**Implant designs; abutment designs**	**Abutment designs PEEK material**	**Abutment designs**
Product Codes	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Implant Designs					
Prosthetic Interface Connections	Morse taper (CM, 11.5°)	Morse taper (CM, various angles)	External hex (HE), Internal hex (HI)	Morse taper (CM, 16°; “GM”)	Morse taper (CM, 11.5°)
Body/Platform Diameters, mm Lengths, mm Interface	**Strong SW / Strong SW Plus** 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 8.5, 10, 11.5, 13, 15 Morse taper interface (CM, 11.5°)	**Strong SW CM** 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 8.5, 10, 11.5, 13, 15 Morse taper interface (CM, 16°)		**Titamax, Helix, and Drive implant lines** 3.5/3.5 – 5.0/5.0 8 – 18 Morse taper (CM, 16°, “GM”)	**Titamax and Alvim implant lines** 3.5/3.5 – 5.0/5.0 8 – 18 Morse taper (CM, 11.5°)
Body/Platform Diameters, mm Lengths, mm Interface		**Unitite, Unitite Slim, Unitite Compact** *Various sizes, 2.9/2.9 to 6.0/6.0* *Various lengths, 5 mm to 15 mm* **Reference for HA^{nano} surface** Morse taper interfaces (CM): Unitite 11.5°, Unitite Slim 3°, Unitite Compact 4°	**Strong SW HE** 3.5/3.65; 3.75/4.1; 4.0/4.1; 4.5/4.5; 5.0/5.0 7*, 8.5, 10, 11.5, 13, 15 ** no 7 mm length for 4.5 mm body* External hex interface (HE)		
Body/Platform Diameters, mm Lengths, mm Interface			**Strong SW HI** 3.8/3.8; 4.5/4.5; 5.0/5.0 8.5, 10, 11.5, 13, 15 Internal hex interface (HI)		
Body/Platform Diameters, mm Lengths, mm Body/Platform Diameters, mm Lengths, mm Body/Platform Diameters, mm Lengths, mm Interface	**Tryon CM Conical** 3.5/3.5, 4.0/4.0; 5.0/5.0 8.5, 10, 11.5, 13, 15 **Tryon CM Cylindrical** 3.5/3.5, 3.75/3.75, 4.0/4.0; 5.0/5.0 7, 8.5, 10, 11.5, 13, 15 **Tryon CM Cylindrical Body and Conical Apex** 3.5/3.5, 3.8/3.8, 4.5/4.5; 5.0/5.0 8.5, 10, 11.5, 13, 15 Morse taper interface (CM, all implants 11.5°)		**Tryon HE** 3.25/4.1; 3.75/4.1; 4.0/4.1; 5.0/5.0 7*, 8.5, 10, 11.5, 13, 15 ** no 7 mm length for 3.25 mm body* External hex interface (HE)		
Implant Placement Level	1.5 mm sub-crestally	Crestally	1-2 mm sub-crestally	Up to 2 mm sub-crestally *(in 510(k) Summary)*	1-2 sub-crestally *(in public labeling)*
Implant Material	All implants: unalloyed titanium, ASTM F67	All implants: unalloyed titanium, ASTM F67	All implants: unalloyed titanium, ASTM F67	Unalloyed titanium	Unalloyed titanium
Implant Endosseous Surface	All implants: acid-etched; HA^{nano} applied to the Strong SW Plus implant line only	All implants: acid-etched; HA^{nano} applied to the Unitite, Unitite Slim, and Unitite Compact dental implant lines	All implants: acid-etched	All implants: grit-blasted, acid etched (“Neoporos”) Selected implants additional hydrophilic treatment (“Acqua”)	All implants: grit-blasted, acid etched (“Neoporos”)

	Subject Device	Primary Predicate Device	Additional Predicate	Additional Predicate	Additional Predicate
	K200992 **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K170392** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K170398** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K163194** **Neodent Implant System - GM Line** **JJGC Indústria e Comércio de Materiais Dentários SA**	**K101945** **Neodent Implant System** **JJGC Indústria e Comércio de Materiais Dentários SA**
Abutment Designs					
Cemented Abutments Morse taper interface (CM, 16°)	**Abutment Cemented Morse Angled** Morse taper interface (CM, 16°) Prosthetic platform Ø: 3.3, 4.5 mm Gingival height: 1.5-3.5 mm Angle 17°, 30° Indexed **Abutment Angled Morse** Morse taper interface (CM, 16°) Prosthetic platform Ø: 3.5, 4.5 mm Gingival height: 1, 2, 3, 4, 5 mm Angle 17° Indexed	**Abutment Cemented Strong SW CM** Morse taper interface (CM 16°) Prosthetic platform Ø 3.5, 4.5 mm Gingival height: 1, 2, 3, 4, 5, mm Angle 0° Non-indexed		**GM Exact Click Universal Abutment** Morse taper interface (CM 16°) Prosthetic platform Ø 3.3, 4.5 mm Gingival height, straight: 0.8-5.5 mm Gingival height, angled: 1.5-3.5 mm Angle Straight (0°), 17°, 30° Indexed	
Mini Abutments Morse taper interface (CM, 16°)	**Abutment Mini Angled Morse** Morse taper interface (CM, 16°) Prosthetic platform Ø: 4.8 mm Gingival height: 2, 3, 4 mm Angle 17°, 30° Indexed and non-indexed	**Mini Abutment Strong SW CM** Morse taper interface (CM 16°) Prosthetic platform Ø 4.8 mm Gingival height: 1, 2, 3, 4 mm Angle 0° Non-indexed		**GM Mini Conical Abutment** Morse taper interface (CM 16°) Prosthetic platform Ø: 4.8 mm Gingival height: 1.5-3.5 mm Angle 17°, 30° Indexed	
Cemented Abutment SIT Morse taper interface (CM, 11.5°)	**Abutment Cemented Angled SIT** Morse taper interface (CM, 11.5°) Prosthetic platform Ø: 3.3, 4.5 mm Gingival height: 1.5-3.5 mm Angle 17°, 30° Non-indexed **Abutment Cemented Angled Indexed SIT** Morse taper interface (CM, 11.5°) Prosthetic platform Ø: 3.3, 4.5 mm Gingival height: 1.5-3.5 mm Angle 17°, 30° Indexed	**Abutment Cemented SIT Unitite** Morse taper interface (CM 11.5°) Prosthetic platform Ø 3.3 mm, 4.5 mm Gingival height: 0.8-5.5 mm Angle 0° Non-indexed			**CM Universal Abutment** Morse taper interface (CM 11.5°) Prosthetic platform – not in 510(k) Summary Gingival height: 1.5-3.5 mm Angle 17°, 30° Indexed and non-indexed
Mini Abutments Morse taper interface (CM, 11.5°)	**Abutment Mini Angled** Morse taper interface (CM, 11.5°) Prosthetic platform Ø: 4.8 mm Gingival height: 1.5-3.5 mm Angle 17°, 30° Indexed and non-indexed	**Mini Abutment Unitite** Morse taper interface (CM 11.5°) Prosthetic platform Ø 4.8 mm Gingival height: 0.8-5.5 mm Angle 0° Non-indexed			**CM Mini Conical Abutment** Morse taper interface (CM 11.5°) Prosthetic platform – not in 510(k) Summary Gingival height: 1.5-3.5 mm Angle 17°, 30° Indexed
Healing Caps Morse taper interface (CM, 16°)	**Healing Cap Morse /** **Healing Cap Morse Indexed** Morse taper interface (CM, 16°) Coronal Ø: 5, 8 mm Gingival Height: 4, 8 mm Non-indexed and indexed PEEK	**Healing Abutment Strong SW CM** Morse taper interface (CM, 16°) Coronal Ø: 3.5, 4.5 mm Gingival Height: 2-6 mm Non-indexed Titanium alloy, ASTM F136		**GM Pro PEEK (Temporary) Abutment** Morse taper interface (CM, 16°) Coronal Ø: 4.5, 6 mm Gingival Height: 0.8-5.5 mm Indexed Titanium alloy and PEEK	
Healing Caps Morse taper interface (CM, 11.5°)	**Healing Cap / Healing Cap Indexed** Morse taper interface (CM, 11.5°) Coronal Ø: 5, 8 mm Gingival Height: 4, 8 mm Non-indexed and indexed PEEK	**Healing Abutment Unitite** Morse taper interface (CM, 11.5°) Coronal Ø: 3.3, 4.5 mm Gingival Height: 0.8-5.5 mm Non-indexed Titanium alloy, ASTM F136			

	Subject Device	Primary Predicate Device	Additional Predicate	Additional Predicate	Additional Predicate
	K200992 **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K170392** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K170398** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K163194** **Neodent Implant System - GM Line** **JJGC Indústria e Comércio de Materiais Dentários SA**	**K101945** **Neodent Implant System** **JJGC Indústria e Comércio de Materiais Dentários SA**
Healing Caps Morse taper interface (CM, 4°)	**Healing Cap Compact /** **Healing Cap Compact Indexed** Morse taper interface (CM, 4°) Coronal Ø: 5, 8 mm Gingival Height: 4, 8 mm Non-indexed and indexed PEEK	**Healing Abutment Unitite Compact** Morse taper interface (CM, 4°) Coronal Ø: 4.0 mm Gingival Height: 2-6 mm Non-indexed Titanium alloy, ASTM F136		**GM Pro PEEK (Temporary) Abutment** Morse taper interface (CM, 16°) Coronal Ø: 4.5, 6 mm Gingival Height: 0.8-5.5 mm Indexed Titanium alloy and PEEK	
Healing Caps Morse taper interface (CM, 3°)	**Healing Cap Slim /** **Healing Cap Slim Indexed** Morse taper interface (CM, 3°) Coronal Ø: 4 mm Gingival Height: 4, 8 mm Non-indexed and indexed PEEK	**Healing Abutment Unitite Slim** Morse taper interface (CM, 3°) Prosthetic platform Ø: 3.3 mm Gingival Height: 1.5-4.5 mm Non-indexed Titanium alloy, ASTM F136			
Healing Caps External hex interface (HE)	**Healing Cap HE / Healing Cap HE Indexed** External hex interface (HE) Platform Ø: 3.4, 3.5, 4.1, 5.0 mm Coronal Ø: 5, 8 mm Gingival Height: 6.8 mm Non-indexed and indexed PEEK		**Healing Abutment** External hex interface (HE) Platform Ø 3.65, 4.1, 5.0 mm Coronal Ø: 4.1, 5.0 mm Gingival height: 2, 4, 6, 8 mm Titanium alloy, ASTM F136 **Cover Screw** External hex interface (HE) Platform Ø 3.4, 3.65, 4.1, 5.0 mm Coronal Ø: 3.5-5.0 mm Titanium alloy, ASTM F136	**GM Pro PEEK (Temporary) Abutment** Morse taper interface (CM, 16°) Coronal Ø: 4.5, 6 mm Gingival Height: 0.8-5.5 mm Indexed Titanium alloy and PEEK	
Healing Caps Internal hex interface (HI)	**Healing Cap HI / Healing Cap HI Indexed** External hex interface (HI) Platform Ø: 3.8, 4.5 mm Coronal Ø: 5, 8 mm Gingival Height: 6.8 mm Non-indexed and indexed PEEK		**Healing Abutment** External hex interface (HI) Platform Ø 3.8, 4.5 mm Coronal Ø: 4, 5 mm Gingival height: 2, 4, 6 mm Titanium alloy, ASTM F136 **Cover Screw** External hex interface (HI) Platform Ø 3.8, 4.5, 5.0 mm Coronal Ø: 3.8, 4.5, 5.0 mm Titanium alloy, ASTM F136	**GM Pro PEEK (Temporary) Abutment** Morse taper interface (CM, 16°) Coronal Ø: 4.5, 6 mm Gingival Height: 0.8-5.5 mm Indexed Titanium alloy and PEEK	
Abutment Materials	Titanium alloy, ASTM F136 PEEK, ASTM F2026	Titanium alloy, ASTM F136 Cobalt-chromium alloy, ASTM F1537	Titanium alloy, ASTM F136 Cobalt-chromium alloy, ASTM F1537	Titanium alloy PEEK	Titanium alloy
Abutment Screw Materials	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy	Titanium alloy
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
Abutments	All sterile by gamma irradiation	All sterile by gamma irradiation, *except:* Provisional, SIT Provisional Cap, and UCLA-type abutments Non-sterile components to be moist heat sterilized by end user	All sterile by gamma irradiation, *except:* Provisional and UCLA-type abutments Non-sterile components to be moist heat sterilized by end user	All sterile by EO exposure	All sterile by EO exposure
Abutment Screws	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by EO exposure	All sterile by EO exposure
Usage	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use