May 14, 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: K193096
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: April 27, 2020
Received: April 28, 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)*
K193096

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.

All digitally-designed custom abutments for use with Interface CAD-CAM abutments are to be sent to a S.I.N.-validated milling center for manufacture.

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
K193096
S.I.N. - Sistema de Implante Nacional S.A.
S.I.N Dental Implant System

May 12, 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:
K170398, S.I.N. Dental Implant System, S.I.N. – Sistema de Implante Nacional S.A.

Reference Devices:
K170392, S.I.N. Dental Implant System, S.I.N. – Sistema de Implante Nacional S.A.
K051859, Sistema de Implante Nacional Dental Implant System, Sistema de Implante Nacional Ltda
K183518, Preat Abutments, Preat Corporation

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.

All digitally-designed custom abutments for use with Interface CAD-CAM abutments are to be sent to a S.I.N.-validated milling center for manufacture.

DEVICE DESCRIPTION

The purpose of this submission is to add to the S.I.N. Dental Implant System components cleared in K170392 and K170398. The K170392 submission included dental implants with a Morse taper abutment interface, mating abutments, abutment screws, and other associated components. Components cleared in K170392 included the Unitite line of dental implants that have a threaded endosseous surface produced by acid-etching followed by application of a hydroxyapatite coating (HA^{nano}). All other dental implants cleared in K170392 had a threaded endosseous surface that was acid-etched only (no HA^{nano}).

This submission adds the following components to the S.I.N. Dental Implant System: the identical HA^{nano} coating to the Strong SW CM (Morse taper) implant line cleared in K170392; the identical HA^{nano} coating to the Strong SW HE (external hexagon) implant line cleared in K170398; the identical HA^{nano} coating to the Strong SW HI (internal hexagon) implant line cleared in K170398; a new implant line, Tryon Conic HE, with an external hexagon abutment interface; a series of conventional (not CAD-CAM) prosthetic components that are compatible with implants from the S.I.N. Dental Implant System; and a series of CAD-CAM prosthetic components for fabrication of patient-specific restorations that are compatible with implants from the S.I.N. Dental Implant System.

Subject Device Implants

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

Implant Line	Body Ø, mm	Platform Ø, mm	Length, mm					
Strong SW CM Plus (Morse Taper) with HA^{nano} surface	3.5	3.5		8.5	10	11.5	13	15
	3.8	3.8		8.5	10	11.5	13	15
	4.5	4.5		8.5	10	11.5	13	15
	5.0	5.0		8.5	10	11.5	13	15
Strong SW HE Plus (External hex) with HA^{nano} surface	3.5	3.65	7	8.5	10	11.5	13	15
	3.75	4.1	7	8.5	10	11.5	13	15
	4.0	4.1	7	8.5	10	11.5	13	15
	4.5	4.5		8.5	10	11.5	13	15
	5.0	5.0	7	8.5	10	11.5	13	15
Strong SW HI Plus (Internal Hex) with HA^{nano} surface	3.8	3.8		8.5	10	11.5	13	15
	4.5	4.5		8.5	10	11.5	13	15
	5.0	5.0		8.5	10	11.5	13	15
Tryon Conic HE (External Hex)	4.0	4.0		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 identical HA^{nano} surface cleared in K170392 (Tryon Conic HE implants so not have the HA^{nano} surface).

Conventional Abutments

The subject device conventional abutments are summarized in the following table.

Types	Platform Ø, mm	Prosthetic Platform Ø, mm	Materials	Compatible with
Universal Cemented Abutment (External hex)	3.65	3.3	Titanium alloy	Implants: Strong SW HE Strong SW HE Plus
Cemented Abutment SIT (Morse Taper, CM)	3.3 4.5	3.3 4.5	Titanium alloy	Implants: Strong SW CM Strong SW CM Plus
Healing Abutment (External hex)	3.65	n/a	Titanium alloy	Implants: Strong SW HE Strong SW HE Plus
Provisional Abutment (External hex)	3.65	n/a	Titanium alloy	Implants: Strong SW HE Strong SW HE Plus
UCLA-type Abutment (External hex)	3.65	4.0	Co-Cr alloy	Implants: Strong SW HE Strong SW HE Plus
UCLA-type Abutment (Internal hex)	3.8 4.5	4.5 4.7	Co-Cr alloy	Implants: Strong SW HI Strong SW HI Plus
Micro-Mini Abutments (External hex)	3.65	3.5	Titanium alloy	Implants: Strong SW HE Strong SW HE Plus
Abutment Protectors	n/a	n/a	Titanium alloy	n/a

All subject device conventional abutments are manufactured from the same titanium alloy or cobalt-chromium alloy materials used to manufacture S.I.N. Dental Implant System conventional abutments cleared in K170398 and K170392. All subject device conventional abutments are provided in straight designs and are not intended for any angulation correction.

Universal Cemented Abutment (HE connection) is a titanium alloy abutment for cement-retained prostheses, provided in gingival heights of 2, 3, and 4 mm, each with a prosthetic post height or 4 mm or 6 mm. The Universal Cemented Abutment with a 4 mm prosthetic post is not to be modified; the Universal Cemented Abutment with a 6 mm prosthetic post may be modified to a minimum height of 4 mm.

Cemented Abutment SIT (CM connection) is a titanium alloy abutment for cement-retained prostheses, provided in a range of gingival heights from 0.8 mm to 5.5 mm (6 heights). The Cemented Abutment SIT is provided with the System Intelligent Transfer (SIT) prosthetic post design, cleared in K170392, that allows for placement of the precision SIT Provisional Cap (also cleared in K170392). The SIT post design is provided in a height of 4 mm and 6 mm.

Healing Abutments (HE connection) are provided in gingival heights of 2, 4, and 6 mm.

Provisional Abutments (HE connection) are titanium alloy abutments for screw-retained or cement-retained provisional restorations. Provisional Abutments are provided in designs for single-unit restorations (anti-rotational design) or multi-unit restorations (rotational design).

UCLA-type Abutment (HE connection; HI connection) are two-part cast-on abutments consisting of a cobalt-chromium alloy base and a polyoxymethylene (POM) burn-out sleeve. The POM burn-out sleeve can be cast in cobalt-chromium alloy or nickel-chromium alloy. UCLA-type Abutments are designed for screw-retained or cement-retained crown and bridge restorations. For the HE connection, the UCLA-type Abutments are provided with a 1 mm gingival height, and for the HI connection, the UCLA-type Abutments are provided with a gingival height of 0.5 mm or 1 mm.

Micro-Mini Abutments (HE connection) are multi-unit, non-indexed abutments, provided in gingival heights of 2, 3, and 4 mm.

Abutment Protectors (HE connection; CM connection) are for the healing period between implant placement and abutment placement. The Abutment Protectors are provided with three interfaces for Morse taper (CM), HE, and Micro-Mini abutments.

CAD-CAM Abutments

The subject device CAD-CAM abutments are summarized in the following table.

Types	Platform Ø, mm	Prosthetic Platform Ø, mm	Materials	Compatible with
Interface Conical Abutment	Matches Conical Abutment; used as extensions/sleeves connected to the coronal geometry of the Conical Abutment to extend the post height	5.5	Co-Cr alloy Titanium alloy	Conical Abutments
Interface Morse Taper Abutment (CM, Strong)	3.5 3.5	3.5 4.25	Titanium alloy	Implants: Strong SW CM Strong SW CM Plus
Interface Morse Taper Abutment (CM, Unitite)	3.5 3.5	3.5 4.25	Titanium alloy	Implants: Unitite CM
Interface External Hex Abutment (HE, Strong, Tryon)	3.4 3.65 4.1 4.1	4.1 4.1 4.3 5.0	Co-Cr alloy Titanium alloy	Implants: Strong SW HE Strong SW HE Plus Tryon
Interface Internal Hex Abutment (HI, Strong)	3.8 3.8	4.1 4.3	Co-Cr alloy Titanium alloy	Implants: Strong SW HI Strong SW HI Plus
Interface Mini Abutments	Matches Mini Abutments; used as extensions/sleeves connected to the coronal geometry of the Mini Abutments to extend the post height	5.5	Co-Cr alloy Titanium alloy	Mini Abutments
Interface Micro Mini Abutments	Matches Micro Mini Abutments; used as extensions/sleeves connected to the coronal geometry of the Micro Mini Abutments to extend the post height	3.8	Co-Cr alloy Titanium alloy	Micro Mini Abutments
Interface External Hex Abutment, non-indexed (HE, Strong, Tryon)	3.65 4.1	4.1 4.3	Co-Cr alloy Titanium alloy	Implants: Strong SW HE Strong SW HE Plus Tryon

The subject device CAD-CAM abutments are used as the apical base of a two-piece abutment. The coronal portion of the two-piece abutment is designed and manufactured using CAD-CAM techniques. For the titanium alloy CAD-CAM abutments, the coronal portion is a coping manufactured from zirconia conforming to ISO 13356 *Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y TZP).* For the Co-Cr alloy CAD-CAM abutments, CAD-CAM is used to design and fabricate

a wax-up model, and the final abutment is cast using traditional techniques as described below.

All subject device CAD-CAM abutments are manufactured from the same titanium alloy or cobalt-chromium alloy materials used to manufacture S.I.N. Dental Implant System abutments cleared in K170398 and K170392. All subject device CAD-CAM abutments are provided in straight designs and are not intended for any angulation correction. No superstructure for use with any titanium alloy subject device CAD-CAM abutment is to be fabricated to create a final abutment with angulation or to correct for angulation. The limits of fabrication for the required superstructure for the titanium alloy CAD-CAM abutments are the same as the limits of fabrication for the superstructure for K183518. The material of the superstructure for the subject device CAD-CAM abutments is zirconia conforming to ISO 13356; this is same zirconia that is specified for superstructures in K183518. Panavia Universal Dual-Cure Cement (Kuraray; Japan) bonding cement is recommended to assemble the zirconia coping to the titanium alloy abutment base.

The Co-Cr alloy CAD-CAM abutments are provided in straight designs and are not intended for any angulation correction. The Co-Cr alloy CAD-CAM abutments will not be fabricated to create a final abutment with angulation or to correct for angulation. The workflow for the Co-Cr alloy abutments is to use CAD-CAM to design and fabricate the desired wax-up model, then use traditional casting to fabricate the final finished abutment; a zirconia coping is not used with the Co-Cr alloy CAD-CAM abutments.

Interface Conical Abutments are abutment-level prosthetic components provided in designs for use with previously-cleared Conical Abutments with external hexagon, internal hexagon, and Morse taper implant interfaces (K051859, K170392, and K170398). Interface Conical Abutments are provided with straight cone in indexed (anti-rotational) or non-indexed designs, and a prosthetic post height of 7.5 mm or 9.5 mm.

Interface Morse Taper Abutments are provided in designs compatible with the Strong implant series Morse taper interface and compatible with the Unitite implant series Morse taper interface, with a prosthetic post height of 4.0, 4.7, or 6.0 mm.

Interface External Hex Abutments are compatible with the HE (external hex) implant interface and are provided with an indexed/anti-rotational design for single-unit restorations. Interface External Hex Abutments are provided with a prosthetic post height of 2.5, 4.0, 4.7, or 6.0 mm.

Interface Internal Hex Abutments are compatible with the HI (internal hex) implant interface and have an indexed/anti-rotational design for single-unit restorations. Interface Internal Hex Abutments are provided with a prosthetic post height of 4.0, 4.7, or 6.0 mm.

Interface Mini Abutments are abutment-level prosthetic components provided in designs for use with previously-cleared Mini Conical Abutments with external hexagon, internal hexagon, and Morse taper implant interfaces (K051859, K170392, and K170398). Interface Mini Abutments are provided with straight, non-indexed cone design and a prosthetic post height of 6 mm or 8 mm.

Interface Micro Mini Abutments are abutment-level prosthetic components provided in designs for use with Micro Mini Conical Abutments with Morse taper implant interfaces cleared in K170392. Interface Micro Mini Abutments are provided with straight, non-indexed cone design and a prosthetic post height of 4 mm or 6 mm.

Interface External Hex Abutments are compatible with the HE (external hex) implant interface and also are provided with a non-indexed/rotational design for multi-unit restorations. The Interface External Hex Abutments with this rotational design are provided with a prosthetic post height of 2.5, 4.0, or 6.0 mm.

Abutment Screws

Four abutments screws are included in this submission, all with the same external thread (M1.8x0.35), in overall lengths of 10.2 mm, 11.2 mm, 12.2 mm, and 13.2 mm. These screws are compatible with Conical Abutments cleared previously in K051859.

PERFORMANCE DATA

The subject device was evaluated and tested as recommended in the FDA guidance documents *Root Form Endosseous Dental Implants and Endosseous Dental Implant Abutments* (issued May 12, 2004), and *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (issued June 16, 2016).

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: sterilization validation according to ISO 11137-1, 11137-2, 17665-1, and 17665-2 (referenced from K170398 and K170392); bacterial endotoxin testing and shelf life testing (referenced from K170398 and K170392); biocompatibility data for the ASTM F136 titanium alloy and ASTM F1537 Co-Cr alloy (referenced from K170398 and K170392); and biocompatibility testing for the ISO 13356 zirconia material used to fabricate copings for the titanium alloy CAD-CAM abutments (cytotoxicity testing according to ISO 19003-5).

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 Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate K170398 and the reference device K170392; 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.

The minor differences between the IFUS for the subject device and the primary predicate K170398 include the requirement for a validated milling center (subject device), and language concerning Revolution Compact implant (K170398). Minor differences between the IFUS for the subject device and the reference device K170392 include the exact wording regarding immediate loading, the requirement for a validated milling center (subject device), and language concerning implants less than 7 mm in length. Minor differences between the IFUS for the subject device and the reference device K051859 include the exact wording regarding single-unit or multi-unit restorations (subject device) or “crowns, bridges, or overdentures (K051859), and language concerning immediate loading. Minor differences between the IFUS for the subject device and the reference device K183518 included the specific

description of the abutments in K183518, specific language regarding the validated milling center, and the list of compatible OEM implant systems.

None of these minor differences impact safety or effectiveness because both IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

Subject Device Dental Implants

The subject device Strong SW CM Plus implants are identical in design and sizes to the Strong SW CM implants cleared in K170392, and have the identical HA^{nano} surface also cleared in K170392.

The subject device Strong SW HE Plus implants are identical in design and sizes to the Strong SW HE implants cleared in K170398, and have the identical HA^{nano} surface cleared in K170392.

The subject device Strong SW HI Plus implants are identical in design and sizes to the Strong SW HI implants cleared in K170398, and have the identical HA^{nano} surface cleared in K170392.

The subject device Tryon Conic HE implants are substantially equivalent in design and sizes to the TryOn HE implants cleared in K170398. The Tryon Conic HE implants have similar designs, the same external hex interface, and the same range of body/platform sizes and lengths as the predicate device TryOn HE implants.

The subject device dental implants are made of the same unalloyed titanium as the dental implants cleared in K170398 and K170392, and the identical HA^{nano} surface cleared in K170392 (all implants except Tryon Conic HE).

Subject Device Conventional Abutments

All subject device conventional abutments are manufactured from the same titanium alloy or cobalt-chromium alloy materials used to manufacture S.I.N. Dental Implant System conventional abutments cleared in K170398 and K170392.

The subject device conventional abutments with an external hex interface (Universal Cemented Abutments, Healing Abutments, Provisional Abutments, UCLA-type Abutments) are substantially equivalent to the corresponding abutment designs (with an external hex interface) cleared in K170398, having the same sizes or ranges of sizes for platform diameter, prosthetic platform diameter, and gingival height.

The subject device Cemented Abutment SIT with a Morse taper (CM) interface is substantially equivalent to the corresponding abutment design, Abutment Cemented SIT (with CM interface) cleared in K170392, having the same sizes or ranges of sizes for platform diameter, prosthetic platform diameter, and gingival height. The subject device Cemented Abutment SIT with gingival heights of 0.8 mm and 5.5 mm are substantially equivalent to the range of gingival heights for the Conical Abutments (CM interface) also cleared in K170392.

The subject device UCLA-type Abutment with an internal hex (HI) interface is substantially equivalent to the corresponding UCLA-type Abutment with HI interface cleared in K051859, having the same sizes for platform diameter, prosthetic platform diameter, and gingival height. The subject device UCLA-type

Abutment, HI interface with a gingival height of 1 mm is substantially equivalent to the gingival height of the UCLA-type Abutment with external hex (HE) interface cleared in K170398.

The subject device Micro-Mini Abutment with an external hex (HE) interface is substantially equivalent to the Micro-Mini Abutment with CM interface cleared in K170392, having the same sizes or ranges of sizes for prosthetic platform diameter and gingival height.

The subject device Abutment Protectors with external hex (HE) and internal hex (HI) interfaces are substantially equivalent to Abutment Protectors with HE and HI interfaces cleared in K170398. The subject device Abutment Protectors with a Morse taper (CM) interface are substantially equivalent to Abutment Protectors with a CM interface cleared in K170392. The subject device Abutment Protectors have the same ranges of sizes for platform diameter and maximum diameter as the devices cleared in K170398 and K170392, except for the components with a 6 mm maximum diameter. Because the Abutment Protectors are temporary healing covers, this minor difference in diameter does not impact substantial equivalence.

Subject Device CAD-CAM Abutments

The subject device Interface Conical Abutments are abutment-level prosthetic components that are substantially equivalent to corresponding prosthetic components used with Conical Abutments cleared in K170398 (external hex interface), K170392 (Morse taper interface), and K051859 (external hex and internal hex interfaces). The subject device Interface Conical Abutments have the same sizes or ranges of sizes for platform diameter, prosthetic platform diameter, and gingival height as the predicate device and reference devices. Because the Interface Conical Abutments are abutment-level prosthetic components that are incorporated into the final restoration, the minor difference in prosthetic platform diameter (of the subject device compared to the predicate device and reference devices) does not impact safety, effectiveness, or substantial equivalence. The subject device Interface Conical Abutments are manufactured from the same titanium alloy as the devices cleared in K170398 and K070392, or are manufactured from the same cobalt-chromium alloy as the devices cleared in K051859.

The subject device Interface Morse Taper Abutments for the Strong SW CM and Strong SW CM Plus implants are substantially equivalent in material, design, and sizes or ranges of sizes to the Abutment Cemented (SIT/Prepable) Abutments cleared in K170392 for use with Strong SW CM implants.

The subject device Interface Morse Taper Abutments for the Unitite CM implants are substantially equivalent in material, design, and sizes or ranges of sizes to the Abutment Cemented (SIT/Prepable) Abutments cleared in K170392 for use with the Unitite CM implants.

The subject device Interface External Hex Abutments (with an indexed design), are substantially equivalent in materials and designs to the Cemented Abutments and UCLA Abutments with external hex interfaces cleared in K170398 and K051859. The CAD-CAM design feature and range of sizes of the subject device Interface External Hex Abutments (with an indexed design), are substantially equivalent to the Titanium Base Engaging devices cleared in K183518.

The subject device Interface Internal Hex Abutments are substantially equivalent in materials and designs to the Cemented Abutments and UCLA Abutments with internal hex interfaces cleared in K051859. The CAD-CAM design feature and range of sizes of the subject device Interface Internal Hex Abutments are substantially equivalent to the Titanium Base Engaging devices cleared in K183518.

The subject device Interface Mini Abutments are substantially equivalent to the corresponding prosthetic components used with Mini Abutments cleared in K170398 (external hex and internal hex interfaces), K170392 (Morse taper interface), and K051859 (external hex and internal hex interfaces). The subject device Interface Conical Abutments have the same or similar designs as the predicate device and reference devices cited. Because the Interface Mini Abutments are abutment-level prosthetic components that are incorporated into the final restoration, the minor difference in prosthetic platform diameter or gingival height (of the subject device compared to the predicate device and reference devices) does not impact safety, effectiveness, or substantial equivalence. The subject device Interface Mini Abutments are manufactured from the same titanium alloy as the devices cleared in K170398 and K070392, or are manufactured from the same cobalt-chromium alloy as devices cleared in K051859.

The subject device Interface Micro Mini Abutments are substantially equivalent to the corresponding prosthetic components used with the Micro-Mini Abutments cleared in K170392. Because the Interface Micro Mini Abutments are abutment-level prosthetic components that are incorporated into the final restoration, the minor difference in prosthetic platform diameter (of the subject device compared to the cited reference device) does not impact safety, effectiveness, or substantial equivalence. The subject device Interface Mini Abutments are manufactured from the same titanium alloy as the devices cleared in K070392, or are manufactured from the same cobalt-chromium alloy as devices cleared in K051859.

The subject device Interface External Hex Abutments (with a non- indexed design), are substantially equivalent in materials and designs to the Cemented Abutments and UCLA Abutments with external hex interfaces cleared in K170398 and K051859. The CAD-CAM design feature and range of sizes of the subject device Interface External Hex Abutments (with a non-indexed design), are substantially equivalent to the Titanium Base Engaging devices cleared in K183518.

For all subject device CAD-CAM abutments, the limits of fabrication for the required superstructure are the same as the limits of fabrication for the superstructure for K183518. The material for fabrication of the superstructure for the subject device CAD-CAM abutments also is the same zirconia that is specified for superstructures in K183518.

All subject device abutments are provided only in straight designs, with no pre-angled conventional abutments or pre-angled CAD-CAM abutments. No subject device abutment is to be customized to create an angled abutment or to correct for angulation, and no superstructure for use with any subject device CAD-CAM abutment is to be fabricated to create a final abutment with angulation or to correct for angulation. Therefore, minor differences in the exact dimensions of the subject device abutments as compared to the predicate and reference devices does not impact safety, effectiveness, or substantial equivalence.

Similarly, minor differences in the exact dimensions of the subject device dental implants as compared to the predicate and reference devices does not impact safety, effectiveness, or substantial equivalence.

The subject device abutments screws are to be used with Conical Abutments cleared in K051859 and the subject device abutments screws are substantially equivalent in material and designs to abutment screws also cleared in K051859.

Selected conventional abutments manufactured from titanium alloy and all CAD-CAM abutments manufactured from titanium alloy are anodized using a standard anodization process is identical to the anodization process used on abutments cleared in K170398 and K170392.

All subject device dental implants and various abutments and prosthetic components are provided sterile by gamma irradiation, the same as the dental implants in K170398, K170392, and K051859. Abutments and prosthetic components that are provided nonsterile are to be sterilized by the end user by the same validated moist heat sterilization method as in K170398 and K170392.

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 reference device encompass the same range of physical dimensions, are packaged in similar materials, and are sterilized using similar methods.

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

Table of Substantial Equivalence

	Subject Device	**Primary Predicate Device**	**Reference Device**	**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.**	**K170392** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**	**K051859** **Sistema de Implante Nacional Dental Implant System** **Sistema de Implante Nacional Ltda**	**K183518** **Preat Abutments** **Preat Corporation**
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. All digitally-designed custom abutments for use with Interface CAD-CAM abutments are to be sent to a S.I.N.-validated milling center for manufacture.	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.	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.	The Sistema de Implante Nacional Dental Implant System is intended to be surgically placed in the bone of the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures. Implants may be placed immediately after tooth extraction or following bone healing. Restorations supported by two or more Sistema de Implante Nacional implants may be loaded immediately after implant placement if primary implant stability has been achieved.	Preat Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations. The Titanium Base abutments consists of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment. All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Titanium Base or Titanium Blank are to be sent to a Preat validated milling center for manufacture. *(Table of Compatible Implant Systems, see information for K183518 provided in this section)*
Reason for Predicate Device / Reference Device	**Not applicable**	**Implant designs; abutment designs**	**Implant designs; abutment designs; HA^{nano} implant surface**	**Abutment designs**	**Abutment designs**
Product Codes	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	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	External hex (HE), Internal hex (HI), Morse taper (CM)	External hex (HE), Internal hex (HI)	Morse taper (CM)	External hex (HE), Internal hex (HI)	Multiple interface connections (n=10 OEM implant systems)
Body/Platform Diameters, mm Lengths, mm Interface	**Strong SW CM 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)		**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)		
Body/Platform Diameters, mm Lengths, mm Interface	**Strong SW HE Plus** 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)	**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)	**Unitite, Unitite Slim, Unitite Compact** *Various sizes, 2.9/2.9 to 6.0/6.0* *Various lengths, 5 mm to 15 mm* **Reference device for HA^{nano} surface** *Morse taper (different from Strong SW CM)*		
Body/Platform Diameters, mm Lengths, mm Interface	**Strong SW HI Plus** 3.8/3.8; 4.5/4.5; 5.0/5.0 8.5, 10, 11.5, 13, 15 Internal hex interface (HI)	**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 Interface	**Tryon Conic HE** 4.0/4.0; 5.0/5.0 8.5, 10, 11.5, 13, 15 External hex interface (HE)	**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 Material	All implants: unalloyed titanium, ASTM F67	All implants: unalloyed titanium, ASTM F67	All implants: unalloyed titanium, ASTM F67		
Implant Endosseous Surface	All implants: acid-etched + HA^{nano} applied, *except* Tryon Conic HE acid-etch only	All implants: acid-etched	All implants: acid-etched; HA^{nano} applied to the Unitite dental implant lines		
Conventional Abutment Designs					
Cemented Abutment	**Universal Cemented Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/3.3 mm Gingival height: 2, 3, 4 mm Titanium alloy, ASTM F136	**Abutment Cemented** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/5 mm Gingival height: 1, 2, 3, 4 mm Titanium alloy, ASTM F136			
Cemented Abutment SIT	**Cemented Abutment SIT** Morse taper interface (CM) Platform/Prosthetic platform Ø: 3.3/3.3, 4.5/4.5 mm Gingival height: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm Titanium alloy, ASTM F136		**Abutment Cemented SIT** Morse taper interface (CM) Prosthetic platform Ø 3.3 mm, 4.5 mm Gingival height: 1, 2, 3, 4, 5, mm Titanium alloy, ASTM F136		

Table of Substantial Equivalence

	Subject Device	Primary Predicate Device	Reference Device	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.**	**K170392** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**	**K051859** **Sistema de Implante Nacional Dental Implant System** **Sistema de Implante Nacional Ltda**	**K183518** **Preat Abutments** **Preat Corporation**
Healing Abutment	**Healing Abutment** External hex interface (HE) Platform Ø: 3.65 mm Prosthetic platform Ø: n/a Gingival height: 2, 4, 6 mm Titanium alloy, ASTM F136	**Healing Abutment** External hex interface (HE) Platform Ø 3.65, 4.1, 5.0 mm Prosthetic platform Ø: n/a Gingival height: 2, 4, 6, 8 mm Titanium alloy, ASTM F136			
Provisional Abutment	**Provisional Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/3.6 mm Gingival height: 1.2 mm Titanium alloy, ASTM F136	**Provisional Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/4.45, 4.1/4.45, 5.0/5.45 mm Gingival height: 1.2 mm Titanium alloy, ASTM F136			
UCLA-type Abutment (External hex)	**UCLA-type Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/4.0 mm Gingival height: 1 mm Cobalt-chromium alloy, ASTM F1537	**UCLA-type Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/4.7, 4.1/4.7 mm Gingival height: 1 mm Cobalt-chromium alloy, ASTM F1537			
UCLA-type Abutment (Internal hex)	**UCLA-type Abutment** Internal hex interface (HI) Platform/Prosthetic platform Ø: 3.8/4.5, 4.5/4.7 mm Gingival heights: 0.5 mm and 1 mm Cobalt-chromium alloy, ASTM F1537			**UCLA-type Abutment** Internal hex interface (HI) Platform/Prosthetic platform Ø: 3.8/4.5, 4.5/4.7, 5.5/5.7 mm Gingival height: 0.5 mm Cobalt-chromium alloy, ASTM F1537	
Micro-Mini Abutments	**Micro-Mini Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/3.5 mm Gingival heights: 2, 3, 4 mm Titanium alloy, ASTM F136		**Micro-Mini Abutment** Morse taper interface (CM) Prosthetic platform Ø: 3.5 mm Gingival heights: 0.8 mm – 5 mm Titanium alloy, ASTM F136		
Abutment Protectors	**Abutment Protectors** For abutments with HE, HI, CM interface Platform Ø: 3.65 mm, 4.8 mm Maximum Ø: 3.65, 4.5, 6 mm Titanium alloy, ASTM F136	**Abutment Protectors** For abutments with HE and HI interface Platform Ø: 4.8 mm Maximum Ø: 5 mm Titanium alloy, ASTM F136	**Abutment Protectors** For abutments with CM interface Platform Ø: 3.5 mm, 4.8 mm Maximum Ø: 3.5 mm, 5 mm Titanium alloy, ASTM F136		
CAD-CAM Abutment Designs					
Interface Conical Abutments	**Fits Conical Abutments** Platform Ø: matches compatible Conical Abutments Prosthetic platform Ø: 5.5 mm Gingival height: 0.35 mm Cobalt-chromium alloy, ASTM F1537 and Titanium alloy, ASTM F136	**Conical Abutments** External hex interface (HE) Platform Ø: 3.65 mm Prosthetic platform Ø: 4.8 mm Gingival height: 1, 2, 3, 4 mm Titanium alloy, ASTM F136	**Conical Abutments** Morse taper interface (CM) Prosthetic platform Ø: 4.8 mm Gingival height: 0.8 mm – 5.5 mm Titanium alloy, ASTM F136	**Conical Abutments** External hex interface (HE) Platform Ø: 4.1 mm, 5.0 mm Internal hex interface (HI) Platform Ø: 3.8, 4.5, 5.5 mm Prosthetic platform Ø: 4.8 mm (all HE, HI) Gingival height: 1, 2, 3, 4 mm (all HE, HI) Unalloyed titanium, ASTM F67	
Interface Morse Taper Abutments	**For Strong SW CM and Strong SW CM Plus Implants** Morse taper interface (CM) Platform/Prosthetic platform Ø: 3.5/3.5, 3.5/4.25 mm Gingival height: 0.5, 0.8, 2, 3 mm Titanium alloy, ASTM F136		**Abutment Cemented (SIT/Prepable) Strong SW CM** Morse taper interface (CM) Platform/Prosthetic platform Ø: 3.5/3.5, 4.5/4.5 mm Gingival height: 1, 2, 3, 4, 5 mm Titanium alloy, ASTM F136		

Table of Substantial Equivalence

	Subject Device	Primary Predicate Device		Reference Device	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.**		**K170392** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**	**K051859** **Sistema de Implante Nacional Dental Implant System** **Sistema de Implante Nacional Ltda**		**K183518** **Preat Abutments** **Preat Corporation**
Interface Morse Taper Abutments	**For Unitite CM Implants** Morse taper interface (CM) Platform/Prosthetic platform Ø: 3.5/3.5, 3.5/4.25 mm Gingival height: 0.5, 0.8, 2, 3 mm Titanium alloy, ASTM F136			**Abutment Cemented (SIT) for Unitite CM** Morse taper interface (CM) Platform/Prosthetic platform Ø: 3.3/3.3, 4.5/4.5 mm Gingival height: 0.8 mm – 5.5 mm Titanium alloy, ASTM F136			
Interface External Hex (HE) Abutments (indexed)	**For Strong SW HE, Strong SW HE Plus, and Tryon Implants** External hex interface (HE) Platform/Prosthetic platform Ø: 3.4/4.1, 3.65/4.1, 4.1/4.3, 4.1/5.0 mm Gingival height: 0.6, 1.0 mm Cobalt-chromium alloy, ASTM F1537 and Titanium alloy, ASTM F136	**Cemented Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/5.0 mm Gingival height: 1–4 mm Titanium alloy, ASTM F136	**UCLA Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/4.7 mm Gingival height: 1 mm Cobalt-chromium alloy, ASTM F1537		**Cemented Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 4.1/5.0, 4.1/6.0, 5.0/5.5, 5.0/6.0 mm Gingival height: 1–4 mm Unalloyed titanium, ASTM F67	**UCLA Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 4.1/4.5, 5.0/5.5 mm Gingival height: 1, 1.2 mm Unalloyed titanium, ASTM F67; Cobalt-chromium alloy, ASTM F1537; Gold alloy	**Titanium Base Engaging** Multiple interface connections (n=10 OEM implant systems) Platform Ø: 3.0 mm – 6.0 mm Prosthetic platform Ø: *not in 510(k) Summary* Gingival height: *not in 510(k) Summary* Titanium alloy, ASTM F136
Interface Internal Hex (HI) Abutments	**For Strong SW HI and Strong SW HI Plus Implants** Internal hex interface (HI) Platform/Prosthetic platform Ø: 3.8/4.1, 3.8/4.3 mm Gingival height: 0.5 mm Cobalt-chromium alloy, ASTM F1537 and Titanium alloy, ASTM F136				**Cemented Abutment** Internal hex interface (HI) Platform/Prosthetic platform Ø: 3.8/3.8, 4.5/5.1, 5.5/6.0 mm Gingival height: 1–4 mm Titanium alloy, ASTM F136	**UCLA Abutment** Internal hex interface (HI) Platform/Prosthetic platform Ø: 3.8/4.5, 4.5/4.9, 5.5/5.9 mm Gingival height: 0.5 mm Cobalt-chromium alloy, ASTM F1537	**Titanium Base Engaging** Multiple interface connections (n=10 OEM implant systems) Platform Ø: 3.0 mm – 6.0 mm Prosthetic platform Ø: *not in 510(k) Summary* Gingival height: *not in 510(k) Summary* Titanium alloy, ASTM F136
Interface Mini Abutments	**For Mini Abutments** Platform Ø: matches Mini Abutments Prosthetic platform Ø: 5.5 mm Gingival height: 0.35 mm Cobalt-chromium alloy, ASTM F1537 and Titanium alloy, ASTM F136	**Mini Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/4.8 mm Gingival height: 1–4 mm Titanium alloy, ASTM F136	**Mini Abutment** Internal hex interface (HI) Platform/Prosthetic platform Ø: 4.5/4.8 mm Gingival height: 1 – 4 mm Titanium alloy, ASTM F136	**Mini Abutments** Morse taper interface (CM) Prosthetic platform Ø: 4.8 mm Gingival height: 0.8 – 5.5 mm Titanium alloy, ASTM F136	**Mini Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 4.1/4.8, 5.0/4.8 mm Gingival height: 1–4 mm Unalloyed titanium, ASTM F67	**Mini Abutment** Internal hex interface (HI) Platform/Prosthetic platform Ø: 3.8/4.8, 4.5/4.8, 5.5/4.8 mm Gingival height: 1 – 4 mm Unalloyed titanium, ASTM F67	
Interface Micro-Mini Abutments	**For Micro Mini Abutments** Platform Ø: matches Micro Mini Abutments Prosthetic platform Ø: 3.8 mm Gingival height: 0.5 mm Cobalt-chromium alloy, ASTM F1537 and Titanium alloy, ASTM F136			**Micro-Mini Abutment** Morse taper interface (CM) Prosthetic platform Ø: 3.5 mm Gingival heights: 0.8 mm – 5 mm Morse taper interface (CM) Titanium alloy, ASTM F136			
Interface External Hex (HE) Abutments (non-indexed)	**For Strong SW HE, Strong SW HE Plus, and Tryon Implants** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/4.1, 4.1/4.3 mm Gingival height: 1.0 mm Cobalt-chromium alloy, ASTM F1537 and Titanium alloy, ASTM F136	**Cemented Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/5.0 mm Gingival height: 1–4 mm Titanium alloy, ASTM F136	**UCLA Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/4.7 mm Gingival height: 1 mm Cobalt-chromium alloy, ASTM F1537		**Cemented Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 4.1/5.0, 5.0/5.5, 5.0/6.0 mm Gingival height: 1–4 mm Unalloyed titanium, ASTM F67	**UCLA Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 4.1/4.5, 5.0/5.5 mm Gingival height: 1, 1.2 mm Unalloyed titanium, ASTM F67; Cobalt-chromium alloy, ASTM F1537	**Titanium Base Non-Engaging** Multiple interface connections (n=10 OEM implant systems) Platform Ø: 3.0 mm – 6.0 mm Prosthetic platform Ø: *not in 510(k) Summary* Gingival height: *not in 510(k) Summary* Titanium alloy, ASTM F136
Abutment Materials	Titanium alloy, ASTM F136 Cobalt-chromium alloy, ASTM F1537 Zirconia (Y-TZP), ISO 13356 (superstructures)	Titanium alloy, ASTM F136 Cobalt-chromium alloy, ASTM F1537		Titanium alloy, ASTM F136 Cobalt-chromium alloy, ASTM F1537	Titanium alloy, ASTM F136 Unalloyed titanium, ASTM F67		Titanium alloy, ASTM F136 Zirconia (Y-TZP), ISO 13356 (superstructures)
Abutment Screw Materials	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136		Titanium alloy, ASTM F136	Titanium alloy, ASTM F136; gold alloy		

Table of Substantial Equivalence

	Subject Device	**Primary Predicate Device**	**Reference Device**	**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.**	**K170392** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**	**K051859** **Sistema de Implante Nacional Dental Implant System** **Sistema de Implante Nacional Ltda**	**K183518** **Preat Abutments** **Preat Corporation**
How Provided					
Implants	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, *except:* Provisional and UCLA-type abutments; CAD-CAM abutments in cobalt-chromium alloy 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 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	All provided non-sterile To be moist heat sterilized by end user
Abutment Screws	All sterile by gamma irradiation, *except:* Screws for UCLA-type abutments Non-sterile components to be moist heat sterilized by end user	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	All provided non-sterile To be moist heat sterilized by end user
Usage	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use