December 15, 2022

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

Re: K221453
Trade/Device Name: S.I.N. Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 14, 2022
Received: November 15, 2022

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 -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221453

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.

S.I.N. Dental Implant System implants with lengths of 18, 20, 22, or 24 mm may be tilted up to 30°. When used in the mandible or maxilla with implants with lengths of 18, 20, 22, or 24 mm at an angulation of 30°, a minimum of four implants must be used and must be splinted. When placed in the maxilla with lengths of 18, 20, 22, or 24 mm at angulations between 0° and less than 30°, the S.I.N. Dental Implant System implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

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.

510(k) Summary
K221453
S.I.N. - Sistema de Implante Nacional S.A.
S.I.N Dental Implant System

December 14, 2022

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 Dental Devices and ENT

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K222231, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.
Reference Devices
K211921, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.
K193096, 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.
K200992, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.

INDICATIONS FOR USE STATEMENT

S.I.N. Dental Implant System 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 may be tilted up to 30°. When used in the mandible or maxilla with implants with lengths of 18, 20, 22, or 24 mm at an angulation of 30°, a minimum of four implants must be used and must be splinted. When placed in the maxilla with lengths of 18, 20, 22, or 24 mm at angulations between 0° and less than 30°, the S.I.N. Dental Implant System implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

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.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to add components to the S.I.N. Dental Implant System, which includes components cleared previously in K211921, K203725, K200992, K193096, K170398, K170392, and K051859.

This submission includes dental implants Epikut CM with a Morse taper (CM) abutment interface and an acid-etched endosseous surface, and Epikut Plus CM implants with an endosseous surface produced by acid-etching followed by application of a hydroxyapatite coating (HA^{nano}). The implant design and endosseous surfaces are identical to those cleared in K211921, with the exception of the additional body/platform diameter (4.0 mm) and the longer lengths (18, 20, 22, and 24 mm).

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

Implant Lines	**Body Ø, mm**	**Platform Ø, mm**	**Lengths, mm**			
Epikut CM **Epikut Plus CM**	3.8	3.8	18	20	22	24
	4.0	4.0	18	20	22	24
	4.5	4.5	18	20	22	24

This submission includes Multifunctional Abutments with Morse taper connections (16°, 11.5°, and 4°), and protectors and temporary cylinders for these abutments; the subject device Multifunctional Abutments are compatible with subject device implants (CM 11.5°) and previously-cleared implants (CM 16° and 4°). This submission also includes Multifunctional Abutment components (cylinders) manufactured from Co-Cr-Mo alloy compatible with the subject Multifunctional Abutments and with abutments cleared in K170392; CAD-CAM abutment components (called “Interface”) manufactured from Ti-6Al-4V alloy and Co-Cr-Mo alloy, compatible with the subject Multifunctional Abutments and with abutments cleared in K170392; and screws compatible with subject device components and previously cleared components with the 11.5° Morse taper connection. All subject device abutments are straight, with no angulation allowed. The subject device abutments and prosthetic components are summarized in the following table.

Abutment	Connection	Prosthetic Platform diameter, mm	Gingival Height, mm	Material
Multifunctional	CM 16°, CM 11.5°, CM 4° implants	4.8	0.8-5.5	Ti-6Al-4V
Protector for Multifunctional	n/a	n/a	n/a	Ti-6Al-4V
Temporary Cylinder Abutment	Micro Mini, Multifunctional	3.5, 4.8	0.2-0.5	Ti-6Al-4V
Chrome Cobalt Multifunctional	Multifunctional	5.0	0.5-2.0	Co-Cr-Mo
Chrome Cobalt Micro Mini	Micro Mini	3.3	2.0	Co-Cr-Mo
Interface Titanium Multifunctional	Multifunctional	5.5	0.35	Ti-6Al-4V
Interface Titanium Micro Mini	Micro Mini	3.8	0.5	Ti-6Al-4V
Interface Chrome Cobalt Multifunctional	Multifunctional	5.5	0.35	Co-Cr-Mo
Interface Chrome Cobalt Micro Mini	Micro Mini	3.8	0.5	Co-Cr-Mo
Screw for Protector Multifunctional	Multifunctional	n/a	n/a	Ti-6Al-4V
Screws for Temporary Cylinder Multifunctional; Interface Titanium Multifunctional; Cobalt Chrome Multifunctional; Interface Titanium Multifunctional; Interface Chrome Cobalt Multifunctional	Multifunctional	n/a	n/a	Ti-6Al-4V

For the Abutment Chrome Cobalt Multifunctional and Abutment Chrome Cobalt Micro Mini, the design limit parameters are:

Wall thickness of the final abutment before glazing must be at least 1.1 mm (0.3 mm after casting + 0.8 mm overlay)
Gingival margin diameter must be at least 0.5 mm beyond the prosthetic platform of the abutment.
Gingival margin height must be at least 1 mm up to 3 mm.
Height of the abutment post must be between 4-9.5 mm.
Maximum angle – 0°, Straight only

For the Interface Titanium Multifunctional and Interface Titanium Micro Mini abutments, the design limit parameters are:

Minimum wall thickness – 0.5 mm
Minimum post height for single-unit restoration – 4.0 mm
Maximum angle – 0°, Straight only
Maximum gingival height – 5.0 mm
Minimum Gingival height of superstructure – 0 mm (gingival height provided by underlying apical base)
Maximum allowable Post Height – 6 mm
Total abutment height – 10 mm

For the Interface Chrome Cobalt Multifunctional and Interface Chrome Cobalt Micro Mini abutments, the design limits are:

Minimum wall thickness – 0.5 mm
Minimum post height for single-unit restoration – 4.0 mm
Maximum angle – 0°, Straight only
Maximum gingival height – 5.0 mm
Minimum Gingival height – 0 mm (gingival height provided by underlying apical base)
Maximum allowable Post Height – 6 mm
Total abutment height – 10 mm

All subject device dental implants are manufactured from unalloyed titanium conforming to ASTM F67. 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 K211921, and the HA^{nano} surface treatment is identical to that cleared in K211921.

The subject device implants are compatible with abutments and prosthetic components in this submission and components cleared previously in K200992, K193096, K170398, K170392, and K051859.

The subject device abutments and prosthetic components are compatible with implants and components in this submission and components cleared previously in K211921, K200992, K193096, and K170392.

PERFORMANCE DATA

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

gamma irradiation sterilization for subject devices provided sterile to the end user 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 K211921 and K203725);

bacterial endotoxin testing (referenced from K211921) 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 K211921) 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;

moist heat sterilization for subject devices provided non-sterile to the end user to a sterility assurance level of 10^{-6} by the overkill method according to ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO TIR 17665-2 (referenced from K193096);

biocompatibility testing according to ISO 10993-5 (cytotoxicity) for the implant material ASTM F67, for the abutment and prosthetic component material ASTM F136, and for the abutment material ASTM F1537 (all provided in K170398);

biocompatibility testing according to ISO 10993-5 (cytotoxicity) for zirconia coping material ISO 13356 provided in K193096;

biocompatibility testing and characterization of the HAnano hydroxyapatite coating leveraged from K211921 (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 HAnano hydroxyapatite coating leveraged from K211921 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;

characterization of the implant acid-etched surface included scanning electron microscopy (SEM) leveraged from K211921 (provided in K051859);

non-clinical analysis and testing to evaluate the metallic subject devices in the MR environment according to ASTM F2052 (magnetically induced displacement force), ASTM F2213 (magnetically induced torque), ASTM F2182 (RF induced heating), and ASTM F2119 (image artifact), and the FDA guidance document *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* (issued May 2021); and

engineering analysis provided in this submission demonstrated that the subject device implants, in combination with compatible previously-cleared abutments, do not create a new worst-case construct, and that previous mechanical testing conducted according to ISO 14801 (submitted in K200992) is applicable to the subject device implants.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference devices.

The primary predicate device K222231 is for support of substantial equivalence of the implant designs, including implant lengths of 18 mm to 24 mm, materials, manufacturing, and sterilization. The primary predicate K222231 also is for support of substantial equivalence of the Indications for Use statement for implants tilted up to 30°, as described below.

The reference device K211921 also is for support of substantial equivalence of the implant designs (11.5° Morse taper connection), materials, manufacturing, and sterilization.

The reference devices K193096 and K170392 are for support of substantial equivalence of the abutments and prosthetic components as described below.

The Indications for Use Statement (IFUS) for the subject device includes language concerning placement in the maxillary or mandibular arches and regarding immediate loading that is identical to the language in K222231, K211921, K193096, and K170392. The IFUS for the subject device also includes identical language to that included in K222231 regarding longer length implants, and identical language to that included in K193096 regarding CAD-CAM abutments. The IFUS for the subject device includes language that implants may be tilted up to 30°, and language that requires, for an angulation of 30°, a minimum of four (4) implants must be used and must be splinted. This language is identical to the language in the IFUS of the primary predicate device K222231. The IFUS for the subject device also includes language that implants with lengths of 18 mm to 24 mm placed at angulations between 0° and less than 30° are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. This language also is identical to language in the IFUS of the primary predicate device K222231.

Differences between the IFUS for the subject device and the primary predicate device and reference devices include language in the subject device IFUS regarding CAD-CAM abutments that is only applicable to K193096, and language in K170392 regarding implant lengths less than 7 mm that is not relevant to the subject device.

Subject Device Dental Implants

The subject device Epikut CM and Epikut Plus CM implants have nearly identical designs (except for lengths), materials, and manufacturing as used for the Epikut CM and Epikut Plus CM implants cleared in K211921. The subject device Epikut CM and Epikut Plus CM implants have the same 11.5° internal

Morse taper abutment connection and are provided in the same range of body/platform diameters as the implants cleared in K211921; the subject implants are provided in an additional body/platform diameter of 4.0/4.0, which is within the range of the implant sizes cleared in K211921.

The subject device implants are provided in lengths of 18 mm to 24 mm and may be tilted up to 30° for full-arch restorations using a minimum of four (4) implants that must be splinted; these lengths and the requirement for splinting are identical to the primary predicate K222231.

All subject device dental implants are manufactured from the same unalloyed titanium and all have the same acid-etched surface treatment used for the dental implants cleared in K222231 and K211921. The subject device Epikut Plus CM implants have the same acid-etched and HA^{nano} endosseous surface treatment as used for implants cleared in K222231 and K211921.

All subject device implants and selected abutment and prosthetic components are provided sterile by gamma irradiation. The subject devices that are provided sterile have the same sterilization method, packaging, and sterile barrier shelf life as devices cleared in K222231, K211921, K203725, K193096, and K170392.

Subject Device Abutments and Prosthetic Components

The subject devices Abutment Multifunctional with 16°, 11.5°, and 4° Morse taper (CM) connections are substantially equivalent to the Mini Abutment Strong SW CM, Mini Abutment Unitite, and Mini Abutment Unitite Compact, respectively, cleared in K170392. These subject devices are provided in similar designs, the same prosthetic platform diameters, the same gingival heights, and the identical material as the abutments cleared in K170392.

The subject device Abutment Protector (for the subject device Multifunctional Abutments) is substantially equivalent to the Abutment Protectors cleared in K193096 because they are provided in similar design, in the identical material, and have a maximum (coronal) diameter that is within the range of diameters cleared in K193096.

The subject device Provisional Abutments (Temporary Cylinders Micro Mini and Temporary Cylinders Multifunctional) are substantially equivalent to the Abutment Provisional Micro Mini and Abutment Mini Provisional, respectively, cleared in K193096. These subject devices are provided in similar designs, the same prosthetic platform diameters, the same gingival heights, and the identical material as the abutments cleared in K193096.

The subject devices Abutment Chrome Cobalt Multifunctional and Abutment Chrome Cobalt Micro Mini are substantially equivalent to Interface Mini Abutments and Interface Micro Mini Abutments cleared in K193096, and to the Mini Abutment Unitite components cleared in K170392.

The subject Abutment Chrome Cobalt Multifunctional components are provided in similar designs and with a platform to abutment diameter (for connection to the subject device Multifunctional Abutments) as the Interface Mini Abutments cleared in K193096. The gingival height of the subject Abutment Chrome Cobalt Multifunctional components is within the range of gingival height for the Interface Mini Abutments (K193096) and the Mini Abutment Unitite (K170392). The subject Abutment Chrome Cobalt Micro Mini components are provided in similar designs and with a platform to abutment diameter (for connection to the subject device Micro Mini Abutments) as the Interface Micro Mini Abutments cleared

in K193096. The gingival height of the subject Abutment Chrome Cobalt Micro Mini components is within the range of gingival heights for the Mini Abutment Unitite (K170392). The subject devices Abutment Chrome Cobalt Multifunctional and Abutment Chrome Cobalt Micro Mini are manufactured from the identical Co-Cr alloy used for the Interface Mini Abutments and Interface Micro Mini Abutments cleared in K193096.

The subject devices Interface Titanium Abutment Multifunctional, Interface Titanium Micro Mini Abutment, Interface Chrome Cobalt Multifunctional, and Interface Chrome Cobalt Micro Mini 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

The subject devices Interface Titanium Abutment Multifunctional and Interface Titanium Micro Mini Abutment are substantially equivalent to the Interface Mini Abutments and Interface Micro Mini Abutments, respectively, cleared in K193096. These subject devices are provided in similar designs, the same prosthetic platform diameters, the same gingival heights, and the identical material (Ti-6Al-4V alloy) as the abutments cleared in K170392. These subject devices and those referenced from K193096 also require a zirconia coping fabricated by CAD-CAM technology.

The subject devices Interface Chrome Cobalt Multifunctional and Interface Chrome Cobalt Micro Mini are substantially equivalent to the Interface Mini Abutments and Interface Micro Mini Abutments, respectively, cleared in K193096. These subject devices are provided in similar designs, the same prosthetic platform diameters, the same gingival heights, and the identical material (Co-Cr alloy) as the abutments cleared in K170392. These subject devices and those referenced from K193096 also require a zirconia coping fabricated by CAD-CAM technology.

All subject device abutments and prosthetic components are provided sterile by gamma irradiation except the following to be sterilized by moist heat by the end user:

Provisional Abutments (Temporary Cylinder Abutment Multifunctional, and Temporary Cylinder Abutment Micro Mini),
Abutment Chrome Cobalt Multifunctional,
Abutment Chrome Cobalt Micro Mini,
Interface Chrome Cobalt Multifunctional, and
Interface Chrome Cobalt Micro Mini.

For these components to be end-user sterilized, validated instructions are included in the Instructions for Use to be provided to the end user. Similar components to be end-user sterilized were cleared in K193096 and K170392.

Engineering analysis provided in this submission demonstrated that the subject device implants, in combination with compatible previously-cleared abutments, do not create a new worst-case construct, and that prior mechanical testing is applicable to the subject device implants.

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

Feature / Attribute	Subject Device **K221453** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	Primary Predicate Device **K222231** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**	Reference Device **K211921** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	Reference Device **K193096** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	Reference Device **K170392** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**
Indications for Use Statement	S.I.N. Dental Implant System 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 may be tilted up to 30°. When used in the mandible or maxilla with implants with lengths of 18, 20, 22, or 24 mm at an angulation of 30°, a minimum of four implants must be used and must be splinted. When placed in the maxilla with lengths of 18, 20, 22, or 24 mm at angulations between 0° and less than 30°, the S.I.N. Dental Implant System implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. 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. S.I.N. Dental Implant System implants with lengths of 18, 20, 22, or 24 mm may be tilted up to 30°. When used in the mandible or maxilla with implants with lengths of 18, 20, 22, or 24 mm at an angulation of 30°, a minimum of four implants must be used and must be splinted. When placed in the maxilla with lengths of 18, 20, 22, or 24 mm at angulations between 0° and less than 30°, the S.I.N. Dental Implant System implants are only indicated for multiple unit restorations in splinted applications that utilize at least two 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 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. Implants with lengths less than 7 mm are intended for delayed loading only.
Reason for Predicate/Reference Device	Not applicable	Indications for tilting implants up to 30°; implant design; lengths 18 mm to 24 mm; materials; manufacturing; sterilization	Implant design; Morse taper (11.5°) connection; materials; manufacturing; sterilization	Indications for CAD-CAM abutments; conventional and CAD-CAM abutment designs; materials; manufacturing; sterilization	Conventional abutment designs; materials; manufacturing; sterilization
Product Codes	DZE, NHA	DZE	DZE	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, 16°)	Morse taper (CM, 11.5°) and External Hex (HE)		
Body/Platform Diameters, mm Lengths, mm Interface	**Epikut CM** 3.8/3.8; 4.0/4.0; 4.5/4.5 18, 20, 22, 24 for all body diameters Morse taper interface (CM, 11.5°)	**Epikut S** 3.5/3.5, 3.8/3.8; 4.0/4.0; 4.5/4.5, 5.0/5.0 8.5 – 15, all body diameters 18–24, for diameters 3.8, 4.0, 4.5 Morse taper interface (CM, 16°)	**Epikut 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, 11.5°)		
Body/Platform Diameters, mm Lengths, mm Interface	**Epikut Plus CM (**HA^{nano} coating) 3.8/3.8; 4.0/4.0; 4.5/4.5 18, 20, 22, 24 for all body diameters Morse taper interface (CM, 11.5°)	**Epikut S Plus (**HA^{nano} coating) 3.5/3.5, 3.8/3.8; 4.0/4.0; 4.5/4.5, 5.0/5.0 8.5–15, all body diameters 18–24, for diameters 3.8, 4.0, 4.5 Morse taper interface (CM, 16°)	**Epikut Plus CM (**HA^{nano} coating) 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°)		
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} coating applied to the Epikut Plus CM implants	All implants: acid-etched; HA^{nano} coating applied to the Epikut S Plus implants	All implants: acid-etched; HA^{nano} coating applied to the Epikut Plus CM implants		
Conventional Abutment Designs					
	Abutment Multifunctional Morse taper interface CM 16° Prosthetic Platform: Ø 4.8 Gingival Height (GH): 1 mm – 4 mm Straight only, 0° Titanium alloy, ASTM F136				**Mini Abutment Strong SW CM** Morse taper interface (CM 16°) Prosthetic platform Ø: 4.8 mm GH: 1 mm – 4 mm Titanium alloy, ASTM F136

Feature / Attribute	Subject Device K221453 S.I.N. Dental Implant System S.I.N. - Sistema de Implante Nacional S.A.	Primary Predicate Device K222231 S.I.N. Dental Implant System S.I.N. – Sistema de Implante Nacional S.A.	Reference Device K211921 S.I.N. Dental Implant System S.I.N. - Sistema de Implante Nacional S.A.	Reference Device K193096 S.I.N. Dental Implant System S.I.N. - Sistema de Implante Nacional S.A.	Reference Device K170392 S.I.N. Dental Implant System S.I.N. – Sistema de Implante Nacional S.A.
	Abutment Multifunctional Morse taper interface CM 11.5° Prosthetic Platform Ø: 4.8 GH: 0.8 mm – 5.5 mm Straight only, 0° Titanium alloy, ASTM F136				**Mini Abutment Unitite** Morse taper interface (CM 11.5°) Prosthetic platform Ø: 4.8 mm GH: 0.8 mm – 5.5 mm Titanium alloy, ASTM F136
	Abutment Multifunctional Morse taper interface CM 4° Prosthetic Platform Ø: 4.8 GH: 1 mm – 5 mm Straight only, 0° Titanium alloy, ASTM F136				**Mini Abutment Unitite Compact** Morse taper interface (CM 4°) Prosthetic platform Ø: 4.8 mm GH: 1 mm – 5 mm Titanium alloy, ASTM F136
	Abutment Protector For Multifunctional abutments Maximum Ø: 5 mm Titanium alloy, ASTM F136			**Abutment Protectors** For abutments with HE, HI, CM interface Maximum Ø: 3.65 mm – 6 mm Titanium alloy, ASTM F136	
	Provisional Abutments **Temporary Cylinders Micro Mini** Prosthetic Platform Ø: 3.5 mm GH: 0.5 mm Straight only, 0° Titanium alloy, ASTM F136			**Abutment Provisional Micro Mini** Prosthetic Platform Ø: 3.5 GH: 0.5 mm Titanium alloy, ASTM F136	
	Provisional Abutments **Temporary Cylinders Multifunctional** Prosthetic Platform Ø: 4.8 mm GH: 0.2 mm Straight only, 0° Titanium alloy, ASTM F136			**Abutment Mini Provisional** Prosthetic Platform Ø: 4.8 GH: 0.2 mm – 1 mm Titanium alloy, ASTM F136	
	Abutment Chrome Cobalt Multifunctional Cylinders to match subject Multifunctional Abutments Platform to abutment Ø: 4.8 mm Prosthetic Platform Ø: 5 mm GH: 0.5 mm Straight only, 0° Co-Cr-Mo alloy, ASTM F1537			**Interface Mini Abutments** Matches Mini Abutments Platform to abutment Ø: 4.8 mm Prosthetic platform Ø: 5.5 mm GH: 0.35 mm Co-Cr-Mo alloy, ASTM F1537 and Titanium alloy, ASTM F136	**Mini Abutment Unitite** Morse taper interface (CM 11.5°) Prosthetic platform Ø: 4.8 mm GH: 0.8-5.5 mm Titanium alloy, ASTM F136
	Abutment Chrome Cobalt Micro Mini Cylinders to match subject Micro Mini Abutments Platform to abutment Ø: 3.5 mm Prosthetic Platform Ø: 3.3 mm GH: 2 mm Straight only, 0° Co-Cr-Mo alloy, ASTM F1537			**Interface Micro Mini Abutments** Matches Micro Mini Abutments Platform to abutment Ø: 3.5 mm Prosthetic platform Ø: 3.8 mm GH: 0.5 mm Co-Cr-Mo alloy, ASTM F1537 and Titanium alloy, ASTM F136	**Mini Abutment Unitite** Morse taper interface (CM 11.5°) Prosthetic platform Ø: 4.8 mm GH: 0.8-5.5 mm Titanium alloy, ASTM F136
CAD-CAM Abutment Designs					
	Interface Titanium Abutment Multifunctional Matches subject Multifunctional Abutments Prosthetic Platform Ø: 5.5 mm GH: 0.35 mm Straight only, 0° Titanium alloy, ASTM F136			**Interface Mini Abutments** Matches Mini Abutments Prosthetic platform Ø: 5.5 mm GH: 0.35 mm Co-Cr-Mo alloy, ASTM F1537 and Titanium alloy, ASTM F136	
	Interface Titanium Micro Mini Abutment Matches Micro Mini Abutments Prosthetic Platform Ø: 3.8 mm GH: 0.5 mm Straight only, 0° Titanium alloy, ASTM F136			**Interface Micro Mini Abutments** Matches Micro Mini Abutments Prosthetic platform Ø: 3.8 mm GH: 0.5 mm Co-Cr-Mo alloy, ASTM F1537 and Titanium alloy, ASTM F136	

Feature / Attribute	Subject Device **K221453** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	Primary Predicate Device **K222231** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**	Reference Device **K211921** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	Reference Device **K193096** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	Reference Device **K170392** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**
	Interface Chrome Cobalt Multifunctional Matches subject Multifunctional Abutments Prosthetic Platform Ø: 5.5 mm; GH: 0.35 mm Straight only, 0° Co-Cr-Mo alloy, ASTM F1537			**Interface Mini Abutments** Matches Mini Abutments Prosthetic platform Ø: 5.5 mm GH: 0.35 mm Co-Cr-Mo alloy, ASTM F1537 and Titanium alloy, ASTM F136	
	Interface Chrome Cobalt Micro Mini Matches Micro Mini Abutments Prosthetic Platform Ø: 3.8 mm GH: 0.5 mm Straight only, 0° Co-Cr-Mo alloy, ASTM F1537			**Interface Micro Mini Abutments** Matches Micro Mini Abutments Prosthetic platform Ø: 3.8 mm GH: 0.5 mm Co-Cr-Mo alloy, ASTM F1537 and Titanium alloy, ASTM F136	
Abutment Materials	Titanium alloy, ASTM F136 Co-Cr-Mo alloy, ASTM F1537 Zirconia, ISO 13356			Titanium alloy, ASTM F136 Co-Cr-Mo alloy, ASTM F1537 Zirconia, ISO 13356	Titanium alloy, ASTM F136
How Provided					
Implants	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation		
Abutments	All sterile by gamma irradiation *Except the following to be sterilized by moist heat by the end user:* Provisional Abutments (Temporary Cylinder Abutment Multifunctional, Temporary Cylinder Abutment Micro Mini) Abutment Chrome Cobalt Multifunctional Abutment Chrome Cobalt Micro Mini Interface Chrome Cobalt Multifunctional Interface Chrome Cobalt Micro Mini			All sterile by gamma irradiation *Except the following to be sterilized by moist heat by the end user:* Provisional Abutments UCLA-type Abutments Interface Conical Abutments Interface External Hex Abutments Interface Internal Hex Abutments Interface Mini Abutments Interface Micro Mini Abutments	All sterile by gamma irradiation *Except the following to be sterilized by moist heat by the end user:* Provisional Abutments UCLA-type Abutments SIT Provisional Caps
Usage – All Components	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use