S.I.N. - Sistema de Implante Nacional S.A.
% Floyd Larson
President
PaxMed International, LLC
12264 EL Camino Real, Suite 400
San Diego, California 92130

May 31, 2024

Re: K232821
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
Dated: May 8, 2024
Received: May 8, 2024

Dear Floyd Larson:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K232821

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.

Unitite Slim, Unitite, Unitite Compact, Strong SW CM
S.I.N Dental Implant System implants with lengths less than 7 mm are intended for delayed loading only.

Epikut CM, Epikut Plus CM, Epikut S, Epikut S Plus
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.

Epikut CM, Epikut Plus CM, Strong SW CM Plus, Strong SW HE Plus, Strong SW HI Plus
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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K232821
S.I.N. - Sistema de Implante Nacional S.A.
S.I.N Dental Implant System

May 22, 2024

ADMINISTRATIVE INFORMATION

Manufacturer Name	S.I.N. - Sistema de Implante Nacional S.A. Avenida Vereador Abel Ferreira, 2140 São Paulo, São Paulo 03340-000 Brazil Telephone +55-11-21693000 ext 3236
Official Contact	Denise Domiciano, Quality and Regulatory Manager
Representative/Consultant	Floyd G. Larson, MS, MBA Kevin A. Thomas, PhD PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Fax +1 858-792-1236 Email flarson@paxmed.com kthomas@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
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.

Reference Devices
K193096, 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.
K211921, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.
K221453, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.
K222231, 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.

Unitite Slim, Unitite, Unitite Compact, Strong SW CM
S.I.N Dental Implant System implants with lengths less than 7 mm are intended for delayed loading only.

Epikut CM, Epikut Plus CM, Epikut S, Epikut S Plus
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.

Epikut CM, Epikut Plus CM, Strong SW CM Plus, Strong SW HE Plus, Strong SW HI Plus
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 labeling claims for a surface treatment designated HA^{nano}, which is applied to implants of the S.I.N. Dental Implant System, as previously cleared in K170392, K193096, K200992, K211921, K221453, and K222231. The new labeling claims and the information supporting the claims are shown below in *Performance Data*.

The following information is a summary of the designs of the subject device implants, as they have been previously cleared with the HA^{nano} surface treatment. Note that there are no changes to any aspect of the design, nor to the HA^{nano} surface treatment, as described in the respective 510(k) Premarket Notifications referenced above.

The previously cleared implants that are the subject of this submission includes eleven (11) product lines from six (6) 510(k)s. Implant body diameters, platform diameters and lengths for each product line are shown below in **Table 10.1** *Summary of Subject Device Designs and Sizes*.

K170392: Unitite Slim, Unitite, Unitite Compact
K193096: Strong SW CM Plus, Strong SW HE Plus, Strong SW HI Plus
K200992: Strong SW Plus
K211921: Epikut Plus CM, Epikut Plus HE
K221453: Epikut Plus CM (additional lengths)
K222231: Epikut S Plus

Table 10.1 – Summary of Subject Device Designs and Sizes

510k	Implant Line	Image *Not to Scale*	Body Ø, mm	Platform Ø, mm	Length, mm											
K170392	Unitite Slim		2.9	2.9					10	11.5	13					
	Unitite		3.5	3.5				8.5	10	11.5	13	15				
			4.3	4.3				8.5	10	11.5	13	15				
			5.0	5.0				8.5	10	11.5	13	15				
	Unitite Compact		4.0	4.0	5	6	7									
			5.0	5.0	5	6	7									
			6.0	6.0	5	6	7									
K193096	Strong SW CM Plus		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		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		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				
K200992	Strong SW Plus		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				
K211921	Epikut Plus CM		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				
	Epikut Plus HE		3.5	3.65			**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				

510k	Implant Line	Image *Not to Scale*	Body Ø, mm	Platform Ø, mm	Length, mm											
K221453	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
K222231	Epikut S Plus		3.5	3.5				8.5	10	11.5	13	15				
			3.8	3.8				8.5	10	11.5	13	15	18	20	22	24
			4.0	4.0				8.5	10	11.5	13	15	18	20	22	24
			4.5	4.5				8.5	10	11.5	13	15	18	20	22	24
			5.0	5.0				8.5	10	11.5	13	15				

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

PERFORMANCE DATA

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

in vitro testing and animal testing referenced from published literature to support the labeling claims for HA^{nano} included in the submission, as shown below:

Labeling Claim	Reference**	Discussion
The HA^{nano} surface increases the surface wettability.*	Bezerra, et al., 2017	Page 6: Water contact angle was significantly less on HAnano treated titanium surface than on dual acid-etched titanium surface
The HA^{nano} surface is hydrophilic.*	Bezerra, et al., 2017	Page 6: Water contact angle was significantly less on HA^{nano} treated titanium surface than on dual acid-etched titanium surface
In vitro studies using pre-osteoblast cells, evaluating the HAnano coating by assessment of cell signaling dynamics, have demonstrated a greater transition from adhesion/proliferative-related signaling to differentiation-related signaling compared to uncoated titanium, thus culminating in changes in osteogenic gene marker expression, which is important in bone regeneration processes.*	Bezerra, et al., 2017	Page 10, correcting name of surface (HA^{nano} vs. Nano Hydroxyapatite-Blasted)
Cells grown on HAnano surfaces demonstrated a spreading morphology different than that of cells grown on machined surfaces.*	Bezerra, et al., 2017	Page 4, Figure 2 caption, correcting name of surface
The HA^{nano} Surface promotes osteoblast differentiation by significantly upregulating RUNX2 and ALP activity when pre-osteoblasts were grown directly on titanium discs.*	Bezerra, et al., 2017	Page 10
Osteoblasts were observed to have a morphology that spread across the HAnano surface differently than over a hydrophilic dual acid-etched surface (SLActive) in *in vitro* experiments.*	da Silva, et al., 2020	Page 7. "Firstly, our data shows there is a differential behavior of osteoblasts adhering on both surfaces; osteoblast spreads better over HAnano®, while osteoblast on SLActive presented a fusiform morphology."

*Results of *in vitro* testing are not necessarily predictive of human clinical performance.

** References

Bezerra F, Ferreira MR, Fontes GN, da Costa Fernandes CJ, Andia DC, Cruz NC, da Silva RA, Zambuzzi WF. Nano hydroxyapatite-blasted titanium surface affects pre-osteoblast morphology by modulating critical intracellular pathways. *Biotechnol Bioeng*. 2017 Aug;114(8):1888-1898.

da Silva RA, da Silva Feltran G, Ferreira MR, Wood PF, Bezerra F, Zambuzzi WF. The Impact of Bioactive Surfaces in the Early Stages of Osseointegration: An In Vitro Comparative Study Evaluating the HAnano® and SLActive® Super Hydrophilic Surfaces. *Biomed Res Int*. 2020 Sep 13.

Other non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included;

- gamma irradiation sterilization for all subject devices (to a sterility assurance level of 10^{-6} by selecting and substantiating a 25 kGy dose using method VDmax25, according to ISO 11137-1 and ISO 11137-2 (referenced from K211921);
- 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;
- biological evaluation was performed according to ISO 10993-1 and test results leveraged from K170392 for ISO 10993-3 (genotoxicity), ISO 10993-5 (cytotoxicity), ISO 10993-6 (implantation), ISO 10993-10 (sensitization, irritation), and ISO 10993-11 (systemic toxicity) to support biocompatibility of the subject device;
- information for the HA^{nano} hydroxyapatite coating was leveraged from K170392;
- 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).
- Fatigue testing according to ISO 14801 referenced from K170392, K193096, K200992, K211921, K221453, and K222231 is applicable to the subject device.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The primary predicate device K170392 is in support of substantial equivalence for the implant designs, materials, HA^{nano} surface, manufacturing, sterilization, shelf-life and biocompatibility. The reference devices are in support of the specific designs of each of the HA^{nano} coated implants.

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 K170392, K193096, K200992, K211921, K221453 and K222231. The IFUS for the subject device also includes identical language to that included in K221453 and K222231 regarding longer implants and identical language to that included in K170392 regarding short implants.

The IFUS for the subject device includes language that implants may be tilted up to 30°, and language that requires, for implants with lengths of 18, 20, 22 or 24 mm and angulation of 30°, that a minimum of four (4) implants must be used and must be splinted. It also includes language that, when placed in the

maxilla with lengths of 18, 20, 22, or 24 mm at angulations between 0° and less than 30°, implants are indicated only for multiple unit restorations in splinted applications that utilize at least two implants. This language is identical to the language in the IFUS of the reference devices K221453 and K222231.

The basis for the belief of S.I.N. - Sistema de Implante Nacional S.A. that the subject device is substantially equivalent to the predicate devices is summarized in the following Table of Substantial Equivalence.

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

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

Table of Substantial Equivalence

	Subject Device	Primary Predicate Device	Reference Devices				
	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.**	**K193096 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.**	**K211921 S.I.N. Dental Implant System S.I.N. - Sistema de Implante Nacional S.A.**	**K221453 S.I.N. Dental Implant System S.I.N. - Sistema de Implante Nacional S.A.**	**K222231 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. Unitite Slim, Unitite, Unitite Compact, Strong SW CM S.I.N Dental Implant System implants with lengths less than 7 mm are intended for delayed loading only. Epikut CM, Epikut Plus CM, Epikut S, Epikut S Plus 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. Epikut CM, Epikut Plus CM, Strong SW CM Plus, Strong SW HE Plus, Strong SW HI Plus 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.	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.	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. 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 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.
Reason for Predicate Device	Not applicable	Implant design, materials; manufacturing, sterilization	Implant design, materials; manufacturing, sterilization	Implant design, materials; manufacturing, sterilization	Implant design, materials; manufacturing, sterilization	Implant design, materials; manufacturing, sterilization	Implant design, materials; manufacturing, sterilization
Product Code(s)	DZE	DZE, NHA	DZE, NHA	DZE, NHA	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	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla

	Subject Device	Primary Predicate Device	Reference Devices				
	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.**	**K193096** **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.**	**K211921** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K221453** **S.I.N. Dental Implant System** **S.I.N. - Sistema de Implante Nacional S.A.**	**K222231** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**
Designs							
Body/Platform Diameters, mm Lengths, mm	**Unitite Slim** 2.9/2.9 Lengths: 10, 11.5, 13 **Unitite** 3.5/3.5; 4.3/4.3; 5.0/5.0 Lengths: 8.5, 10, 11.5, 13, 15 **Unitite Compact** 4.0/4.0; 5.0/5.0; 6.0/6.0 Lengths: 5, 6, 7 **Strong SW CM Plus** 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 Lengths: 8.5, 10, 11.5, 13, 15 **Strong SW HE Plus** 3.5/3.65; 3.75/4.1; 4.0/4.1; 4.5/4.5; 5.0/5.0 Lengths: 7, 8.5, 10, 11.5, 13, 15 (*7 not for 4.5/4.5*) **Strong SW HI Plus** 3.8/3.8; 4.5/4.5; 5.0/5.0 Lengths: 8.5, 10, 11.5, 13, 15 **Strong SW Plus** 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 Lengths: 8.5, 10, 11.5, 13, 15 **Epikut Plus CM** 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 Lengths: 8.5, 10, 11.5, 13, 15 **Epikut Plus HE** 3.5/3.65; 4.5/4.5/5.0/5.0 Lengths: 7, 8.5, 10, 11.5, 13, 15 (*7 not for 4.5/4.5*) **Epikut Plus CM** 3.8/3.8; 4.0/4.0; 4.5/4.5; 5 Lengths: 18, 20, 22, 24 **Epikut S Plus** 3.5/3.5; 3.8/3.8; 4.0/4.0; 4.5/4.5; 5.0/5.0 Lengths: 8.5, 10, 11.5, 13, 15, 18, 20, 22, 24 (*18, 20, 22, 24 not for 3.5/3.5 and 5.0/5.0*)	**Unitite Slim** 2.9/2.9 Lengths: 10, 11.5, 13 **Unitite** 3.5/3.5; 4.3/4.3; 5.0/5.0 Lengths: 8.5, 10, 11.5, 13, 15 **Unitite Compact** 4.0/4.0; 5.0/5.0; 6.0/6.0 Lengths: 5, 6, 7	**Strong SW CM Plus** 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 Lengths: 8.5, 10, 11.5, 13, 15 **Strong SW HE Plus** 3.5/3.65; 3.75/4.1; 4.0/4.1; 4.5/4.5; 5.0/5.0 Lengths: 7, 8.5, 10, 11.5, 13, 15 (*7 not for 4.5/4.5*) **Strong SW HI Plus** 3.8/3.8; 4.5/4.5; 5.0/5.0 Lengths: 8.5, 10, 11.5, 13, 15	**Strong SW Plus** 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 Lengths: 8.5, 10, 11.5, 13, 15	**Epikut Plus CM** 3.5/3.5; 3.8/3.8; 4.5/4.5; 5.0/5.0 Lengths: 8.5, 10, 11.5, 13, 15 **Epikut Plus HE** 3.5/3.65; 4.5/4.5/5.0/5.0 Lengths: 7, 8.5, 10, 11.5, 13, 15 (*7 not for 4.5/4.5*)	**Epikut Plus CM** 3.8/3.8; 4.0/4.0; 4.5/4.5; 5 Lengths: 18, 20, 22, 24	**Epikut S Plus** 3.5/3.5; 3.8/3.8; 4.0/4.0; 4.5/4.5; 5.0/5.0 Lengths: 8.5, 10, 11.5, 13, 15, 18, 20, 22, 24 (*18, 20, 22, 24 not for 3.5/3.5 and 5.0/5.0*)
Implant/abutment interface	Morse taper (CM) 3°, 4°, 11.5°, 16° External hex (HE), Internal hex (HI)	Morse taper (CM) 3°, 4°, 11.5°, 16° External hex (HE)	Morse taper (CM) 3°, 4°, 11.5°, 16° External hex (HE), Internal hex (HI)	Morse taper (CM) 11.5°	Morse taper (CM) 11.5° External hex (HE)	Morse taper (CM) 11.5°	Morse taper (CM) 16°
Material	Ti (ASTM F67)	Ti (ASTM F67)	Ti (ASTM F67)	Ti (ASTM F67)	Ti (ASTM F67)	Ti (ASTM F67)	Ti (ASTM F67)
Implant Endosseous Surface	Acid-etched, HA^{nano}	Acid-etched, HA^{nano}	Acid-etched, HA^{nano}	Acid-etched, HA^{nano}	Acid-etched, HA^{nano}	Acid-etched, HA^{nano}	Acid-etched, HA^{nano}
How Provided							
Sterility	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation
Usage	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use