August 13, 2025

S.I.N. Implant System LTDA.
Denise Domiciano
Quality and Regulatory Affairs Manager
Rua Soldado Ocimar Gumarães da Silva, 421
São Paulo, SP 03348-060
BRAZIL

Re: K251046
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: April 1, 2025
Received: July 14, 2025

Dear Denise Domiciano:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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)*
K251046

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 implants are 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 24mm 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 restoration in splinted applications that utilize at least two implants.

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
K251046

S.I.N. Implant System LTDA
S.I.N Dental Implant System

August 13th, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name	S.I.N. Implant System LTDA 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 Affairs Manager
Representative/Consultant	S.I.N. Implant System LTDA Avenida Vereador Abel Ferreira, 2140 São Paulo, São Paulo 03340-000 Brazil Telephone: +55-11-21693000 ext 3236 Denise Domiciano, Quality and Regulatory Affairs Manager

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	S.I.N. Dental Implant System
Common Names	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 Dental and ENT Devices

PREDICATE DEVICE INFORMATION

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

Additional Devices
K222231, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.
K201225, Neodent Implant System – GM Helix Implants 7.0 - JJGC Indústria e Comércio de Materiais Dentários S.A.
K150182, Neodent Implant System – JJGC Indústria e Comércio de Materiais Dentários S.A.

INDICATIONS FOR USE STATEMENT

Versalis S and Versalis S Plus 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 implants are 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 24mm may be tilted up to 30º. When used in the mandible or maxilla with implants with lengths of 18, 20, 22 or 24 mm at an angulation of 30º, 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 0º and less than 30º, the S.I.N. Dental Implant System implants are only indicated for multiple unit restoration in splinted applications that utilize at least two implants.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to add components to the S.I.N. Dental Implant System, which includes various endosseous implants with 16° Morse tapers interface connection. This submission adds to the S.I.N. Dental Implants System, the Versalis S implants line.

The Versalis S implant line has the Versalis S and Versalis S Plus implants, and both have a Morse taper connection with an internal 16° cone taper. The Versalis S implants have implant body lengths from 8.5 to 24mm and body diameter Ø from 3.5 to 7.0mm., they are manufactured from unalloyed titanium conforming to ASTM F67, with a double acid-etched surface treatment. The Versalis S Plus implants have implant body lengths from 8.5 to 24mm and body diameter Ø from 3.5 to 7.0mm., they are manufactured from unalloyed titanium conforming to ASTM F67, with a double acid-etched surface treatment plus hydroxyapatite surface coating.

All subject device dental implants are manufactured from unalloyed titanium conforming to ASTM F67 *Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)*, Grade 4. The material used to manufacture the dental implants in this submission (conforming to ASTM F67) is identical to the material used to manufacture the device implants cleared in primary predicate K170392 and in additional predicate K222231.

PERFORMANCE DATA

Non-clinical testing data submitted or relied upon to demonstrate substantial equivalence included: radiation sterilization validation according to ISO 11137-1 and 11137-2 and steam sterilization validation according to ISSO 17665-1 and ISO 17665-2, demonstrating a sterility assurance level (SAL) of 10-6; *Limulus* amebocyte lysate (LAL) testing according to AANSI/AAMI ST 72; Shelf life testing according to ASTM F1980, ASTM F1929, and ASTM F88/F88M; biological evaluation was performed according to ISO 10993-1 and test results leveraged from reference device, K222231 to support biocompatibility of the subject device.

Referenced from K222231, bacterial endotoxin testing including Limulus amebocyte lysate (LAL) test according to ANSI/AAMI ST72 on samples of water used in manufacturing on a weekly basis and on samples from sterilized product on a quarterly basis to demonstrate all sterile product meets a limit of < 20 EU/device;

Referenced from K222231, the shelf life of the subject sterile device components is established at four (4) years, consistent with the shelf life of the previously cleared S.I.N. Dental Implant System (K211921). This duration was supported by real-time aging data, where samples were stored for four years under controlled conditions and subsequently tested to confirm maintenance of sterile barrier integrity and sterility. Testing included evaluations per ASTM F1929 (dye penetration for seal integrity) and ASTM F88/F88M (seal strength of flexible packaging), as well as sterility testing in accordance with ISO 11737-2.

Referenced from K222231, all subject device implants are provided sterile via Co-60 gamma irradiation. The

sterilization process has been validated to achieve a Sterility Assurance Level (SAL) of 10^{-6}, utilizing a substantiated dose of 25 kGy in accordance with ISO 11137-1 and ISO 11137-2, using the VDmax25 method. A dimensional analysis was conducted on features that may present challenges to sterilization, such as surface area, internal geometries, overall length, and surface treatments (acid-etched or acid-etched plus HAnano coating).

Referenced from K222231, the subject device is a permanent, tissue- and bone-contacting implant intended for use greater than 30 days. The dental implants are manufactured from commercially pure unalloyed titanium in compliance with ASTM F67, which is the same material used in the S.I.N. Dental Implant System previously cleared under K211921 and K203725. All implants undergo an acid etching process identical to that used in the aforementioned cleared systems. Additionally, the HAnano surface coating applied to the Versalis S Plus implants is identical to that used in the implants cleared under K222231.

Referenced from K222231, non-clinical analysis and testing to evaluate the metallic subject devices and compatible dental implants 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 Labelling Medical Devices for Safety in the Magnetic Resonance (MR) Environment (issued May 2021).

Referenced from K222231, underwent equivalent fatigue testing in accordance with ISO 14801, applying similar load magnitudes and cycle thresholds. The comparative analysis shows that the subject devices met or exceeded the fatigue resistance performance demonstrated by the reference device under identical or more stringent test conditions. Fatigue testing was conducted on the subject devices according to the requirements of ISO 14801:2016. The subject reports provided demonstrate dynamic loading evaluations under conditions simulating clinical use, using representative worst-case implant/abutment configurations. These evaluations measured performance parameters such as maximum applied load, torque values (N·cm), and number of cycles to failure.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device implants are substantially equivalent to the predicate K170392 implants design, indication for use, prosthetic interface connection, material and acid-etched/Ha^{nano} surface, manufacturing and sterilization. The additional predicate device K222231 is in support of the Indications for use, implants design, prosthetic interface connection, materials and acid-etched/Ha^{nano} surface, manufacturing and sterilization and long length 18-24mm. All subject devices are made of the same materials, unalloyed titanium ASTM F67 and are manufactured in the same facilities using the same manufacturing processes as those cleared in primary predicate K170392. Small differences in language in the Indications for Use Statement between the subject device and the primary predicate K170392 and additional predicate K222231 can occurs but do not change the intended use. Both are implant systems placed in the maxilla or mandible to support single or multiunit prostheses and restore chewing function.

The subject device Versalis S and Versalis S Plus implants have the same 16º internal morse taper abutment connection and are provided in the same diameter and length as the implants cleared in additional predicate K222231. The subject device is provided in additional body/platform diameter of 6.0/5.2 and 7.0/6.1, which is within the range of the implant sizes cleared in K201225. The additional predicate devices K201225 and K150182 cover all the implant size as lengths and diameters.

The language in the Indications for Use Statement (IFUS) for the subject device Versalis S and Versalis S Plus is nearly identical to language in the IFUS of the predicate device K170392 is in support of substantial equivalence such as: description of the device, contraindications, warnings, precautions, adverse effects, surgical complications and shipment and handling. The Instructions for Use in IFUS of the subject device is similar to the additional predicate device K222231.

CONCLUSION

The subject device, the primary predicate device, and the additional predicate devices K222231 have the same intended use, have similar technological characteristics, and are made of identical materials. The subject device, the primary predicate, and the additional predicate devices encompass the same range of physical dimensions, are packaged in same materials, and are sterilized using the same methods. The data included in this submission demonstrates substantial equivalence to the primary predicate device and the additional devices listed above.

Table of Substantial Equivalence

Comparison	Subject Device	Primary Predicate	Additional Predicate	Additional Predicate	Additional Predicate
	S.I.N. Dental Implant System **S.I.N. Implant System LTDA**	**K170392** **S.I.N. Dental Implant System** **S.I.N. Implant System LTDA**	**K222231** **S.I.N. Dental Implant System** **S.I.N. Implant System LTDA**	**K201225** **GM Helix Implants 7.0** **Neodent Implant System**	**K150182** **Neodent Implant System** **Neodent Implant System**
Indications for Use	S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to support 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 24mm may be tilted up to 30º. When used in the mandible or maxilla with implants with lengths of 18, 20, 22 or 24 mm at an angulation of 30º, 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 0º and less than 30º, the S.I.N. Dental Implant System implants are only indicated for multiple unit restoration 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. 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. 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.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.
Reason for Predicate / Reference Devices	Not applicable	Indications for Use; implant designs; materials; manufacturing; sterilization, surface, diameter 3.0 – 5.0mm, lengths 8,5 – 15mm.	Indications for Use; implant designs; materials; manufacturing; sterilization, surface, lengths 18 to 24mm.	Diameter 7.0mm	Diameter 5.0mm with length 18.0mm
Product Codes	DZE	DZE, NHA	DZE, NHA	DZE	DZE, NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	The Neodent Implant System is intended to be urgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function.
Implant Designs					
Prosthesis Attachment	Screw-retained Cement-retained	Screw-retained Cement-retained	Screw-retained	Screw-retained	Screw-retained
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Prosthetic Interface Connections	Morse Taper (MT, 16º)	Morse Taper	Morse Taper (MT, 16º)	Grand Morse	Morse Taper
Body/Platform	**Versalis S** 3.5/3.5, 3.8/3.8, 4.0/4.0, 4.3/4.3, 5.0/5.0,	**Strong SW CM** 3.5/3.5, 3.8/3.8, 4.5/4.5, 5.0/5.0	**Epikut S** 3.5/3.5, 3.8/3.8, 4.0/4.0, 4.5/4.5, 5.0/5.0	7.0	3.5, 4.3 and 5.0

Diameters, mm	6.0/5.2, 7.0/6.1				
Lengths, mm	8.5, 10.0, 11.5, 13.0 for diameter 6.0 and 7.0 8.5, 10.0, 11.5, 13.0, 15.0, 18.0 for diameter 3.5 and 5.0 8.5, 10.0, 11.5, 13.0, 15.0, 18.0, 20.0, 22.0, 24.0 for diameter 3.8, 4.0 and 4.3	8.5, 10, 11.5, 13, 15	8.5, 10, 11.5, 13 and 15, all body diameters. 18, 20, 22 and 24, for diameters 3.8, 4.0, 4.5	8; 10; 11.5; 13	18.0
Interface	Morse taper interface (MT, 16º)	Morse taper interface (CM)	Morse taper interface (MT, 16º)	Grand Morse	Morse Taper
	Versalis S Plus	**Strong SW CM**	**Epikut S Plus**		
Body/Platform Diameters, mm	3.5/3.5, 3.8/3.8, 4.0/4.0, 4.3/4.3, 5.0/5.0, 6.0/5.2, 7.0/6.1	3.5/3.5, 3.8/3.8, 4.5/4.5, 5.0/5.0	3.5/3.5, 3.8/3.8, 4.0/4.0, 4.5/4.5, 5.0/5.0	7.0	3.5, 4.3 and 5.0
Lengths, mm	8.5, 10.0, 11.5, 13.0 for diameter 6.0 and 7.0 8.5, 10.0, 11.5, 13.0, 15.0, 18.0 for diameter 3.5 and 5.0 8.5, 10.0, 11.5, 13.0, 15.0, 18.0, 20.0, 22.0, 24.0. for diameter 3.8, 4.0 and 4.3.	8.5, 10, 11.5, 13, 15	8.5, 10, 11.5, 13 and 15 all body diameters. 18, 20, 22 and 24, for diameters 3.8, 4.0, 4.5.	8; 10; 11.5; 13	18.0
Interface	Morse taper interface (MT, 16º)	Morse taper interface (CM)	Morse Taper interface (MT, 16º)	Grand Morse	Morse Taper
Implant Endosseous Surface	**Versalis S** All implants: Acid-Etched	**Strong SW CM** Acid-Etched	**Epikut S** All-implants: acid-etched;		
Implant Endosseous Surface	**Versalis S Plus** All implants: Acid-Etched and Hanano	**Unitite** All implants: Acid-Etched and Hanano	**Epikut S Plus** Acid-Etched and Hanano applied to the Epikut S Plus implants		
Implant Material	All-implants: unalloyed titanium ASTM F67	All-implants: unalloyed titanium ASTM F67	All-implants: unalloyed titanium ASTM F67	Commercially pure Titanium grade 4 (ASTM F67)	Commercially pure Titanium grade 4 (ASTM F67)
How Provided					
Implants	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation