S.I.N. Implant System LTDA
% Michael Davis
Owner/Principal Consultant
Michael Davis Quality and Regulatory Consulting, LLC
204 Norwick Forest Drive
Alabaster, Alabama 35007

November 7, 2025

Re: K251129
Trade/Device Name: S.I.N. Tapered Pro Conical Zygoma Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: Arpil 11, 2025
Received: October 9, 2025

Dear Michael Davis:

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)*
K251129

Device Name
S.I.N. Tapered Pro Conical Zygoma Implant System

Indications for Use *(Describe)*
Pro Zygoma Implants
Pro Zygoma dental implants are intended for placement in the maxillary arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae. The Pro Zygoma dental implants may be used with single-stage or two-stage procedures and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K251129
S.I.N. Implant System LTDA
S.I.N. Tapered Pro Conical Zygoma Implant System
November 6, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name	S.I.N. Implant System LTDA Rua Soldado Ocimar Guimarães da Silva, 421 São Paulo 03348-060 Brazil Telephone: +55 11-21693000 ext 3236
Official Contact	Denise Domiciano Quality and Regulatory Manager
Representative/Consultant	Michael Davis Michael Davis Quality and Regulatory Consulting, LLC 204 Norwick Forest Drive Alabaster, AL 35007 Telephone: +1 205-789-8154 Email: mdavisqandrconsulting@gmail.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	S.I.N. Tapered Pro Conical Zygoma Implant System
Common Name	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 and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K231127, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.

Reference Devices
K240609, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.
K240187, Tapered Pro Conical Implant System, BioHorizons Implant Systems, Inc.
K232099, Neodent Implant System - GM Zygomatic Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A.

INDICATIONS FOR USE STATEMENT

Pro Zygoma Dental Implants

Pro Zygoma dental implants are intended for placement in the maxillary arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae. The Pro Zygoma dental implants may be used with single-stage or two-stage procedures and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to seek initial clearance for S.I.N. Tapered Pro Conical Zygoma Implant System which includes various endosseous dental implants and corresponding prosthetic components. S.I.N. Tapered Pro Conical Zygoma Implant System adds to the S.I.N. Dental Implant System, which includes several components previously cleared in K231127 and K240609, as well as other features of the Tapered Pro Conical Implant System previously cleared in K240187. This submission includes Pro Zygoma dental implants for placement in the maxillary arch, with corresponding Pro Conical Multi-unit Abutments with up to 60° angulation.

The subject Pro Zygoma dental implants have an internal conical abutment connection, with a 15° cone taper. The Pro Zygoma dental implants are provided with body/platform diameters of 3.8 and 4.2 mm, and each body/platform size is provided in overall lengths of 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5 and 60 mm. For all implants, the threads start at the apex and extend 16.8mm coronally.

The external machined surface of the subject Pro Zygoma implants, as well as the external surface of the Pro Conical Angled multi-unit abutments are colored yellow for aesthetic and identification purposes by a standard anodization process in which the devices are submerged in an electrolytic solution and exposed to an electric current to increase the thickness of the natural oxide layer on the surface and impart a distinctive color. No dyes are used in this process. The multi-unit abutment screw (part number SCMUAS) is anodized blue by the same process. The anodization process for the subject Pro Zygoma implants is identical to that used on the reference implant devices cleared in K240187. The anodization process for the subject Pro Conical Angled multi-unit abutments and multi-unit abutment screw is identical to that used on the primary predicate abutment devices cleared in K231127.

Resorbable Blast Texturing (RBT) is applied to the threaded surface of all subject device implants creating a random, roughened texture which increases the implant surface area and helps achieve hard tissue (bone) attachment with the implant. RBT is the application, under pressure, of biocompatible hydroxylapatite (HA) particles (conforming to ASTM F1185 *Standard Specification for Composition of Hydroxylapatite for Surgical Implants*) to the exterior of the machined implant threads. Not to be confused with HA coating, RBT processing uses HA particles to blast the implant surface without depositing HA onto the surface. The HA used for RBT processing does not remain on the surface post-processing. HA media grain size is between 180 – 300 µm for the surface trademarked as RBT (surface finish at 60 Ra minimum).

The subject Pro Conical Angled abutments are multi-unit, indexed abutments for use only with the subject Pro Zygoma implants. The 45°, 52° and 60° Pro Conical Angled Multi-unit Abutments have a prosthetic platform diameter of 4.8 mm, and a gingival height ranging from 1.5 mm to 3.0 mm and are designed only for use with the Pro Zygoma implants. The internal conical implant-abutment connection of the subject devices is identical to that of the BioHorizons reference devices included in K240187, thus the subject Pro Zygoma dental implants are fully compatible with the BioHorizons Conical Multi-unit Angled Abutments (17° and 30°).

All subject dental implants are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136. All subject implants have a resorbable blast textured (RBT) surface treatment, identical to that cleared in K240187. All subject multi-unit abutments are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136. All subject implants and abutments are provided sterile to the end user.

PERFORMANCE DATA

Non-clinical data provided in this submission in support of a determination of substantial equivalence include:

- mechanical testing conducted on a worst-case implant-abutment constructs using a modified version of ISO 14801, compared to a predicate devices, demonstrate that the subject S.I.N. Pro Zygoma Dental Implants when mated with the subject device abutments have sufficient strength for the intended use.

No new verification/validation testing is required to establish substantial equivalence of the subject devices with the compatible BioHorizons Pro Conical 17° and 30° Multi-unit Abutments. The subject device abutments share identical mating geometry with the existing compatible abutments, confirmed by replication of critical specifications provided by the compatible device manufacturer and referenced 510(k) clearances.

Non-clinical data referenced from prior submissions in support of substantial equivalence includes:

- 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 Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* (issued May 2021);
- referenced from K231127, gamma irradiation sterilization validation for all subject devices to a sterility assurance level of 10-6 by selecting and substantiating a 25 kGy dose using method VDmax 25 according to ISO 11137-1 and ISO 11137-2;
- referenced from K231127, 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 K231127, sterile barrier shelf life data;
- referenced from K231127, biocompatibility data for the subject device materials (ASTM F136); and
- referenced from K240187, the implant surface treatment (RBT blast with hydroxyapatite).

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.

Pro Zygoma

The primary predicate device K231127 and reference device K240609 are in support of substantial equivalence of the Indications for Use, implant designs, abutment designs, materials, manufacturing, sterilization, and shelf life to the subject Pro Zygoma dental implants. The reference device K240187 is in support of substantial equivalence of the prosthetic interface connection and implant endosseous surface treatment to the subject Pro Zygoma dental implants.

The language in the Indications for Use Statement (IFUS) for the subject Pro Zygoma dental implants is nearly identical to that of the reference device K240609. The subject device IFUS is similar to the IFUS of the primary predicate device K231127 in terms of use in the maxillary arch (for the subject Pro Zygoma dental implants), and the language regarding immediate loading when good primary stability is achieved and with appropriate occlusal loading.

The implant body diameters, platform diameters, and lengths of the subject Pro Zygoma dental implants are substantially equivalent to the body diameters and lengths of the implants cleared in the primary predicate device

K231127 and the reference device K240609. The subject Pro Zygoma dental implants have the same lengths as the implants cleared in K231127 and K240609. The smallest subject Ø3.8mm Pro Zygoma implant body is smaller than that of the primary (K231127) and reference (K240609) S.I.N. predicate devices. The subject device includes implant lengths up to 60mm which is longer than the Neodent (K232099) reference device maximum length of 55mm. The combination of the smaller implant body diameter and longer length as compared to the primary and reference devices does not raise new questions of safety or effectiveness, as demonstrated by the supporting fatigue testing provided showing superior strength and due to the similarities in threaded lengths and intended placement locations. While the threaded length of the subject device is 0.2mm shorter than the primary predicate device, the reference devices cleared in K232099 have a threaded length of approximately 15mm (based on available implant images). With the reference predicate having a smaller diameter and shorter threaded length than the subject devices, the 3.8mm diameter subject device with 16.8mm of threaded length does not constitute a new worst case and raises no new questions with regard to safety or effectiveness. Finally, the primary K231127 and reference K240609 and K232099 predicates supports substantial equivalence of the Indications for Use to the subject Pro Zygoma dental implants.

The subject Pro Zygoma dental implants are initially packaged in a titanium alloy vial with a titanium alloy cap. Secondary packaging consists of a polyethylene terephthalate blister pack with a Tyvek cover and the appropriate label. The secondary packaging materials are equivalent to those used for the primary predicate device K231127.

All implants and abutments

The subject device implants are substantially equivalent to the implants cleared in the primary predicate device K231127 and reference device K240187 in terms of materials, prosthetic interface connection, endosseous implant surface (RBT blast with hydroxylapatite), manufacturing, packaging, sterilization, and shelf life.

The subject device abutments are made of the same material and have the same conical taper connection (15°) as the abutments cleared in the reference device K240187. The subject device abutments have the same prosthetic platform diameter (4.8 mm), and angulation (45°, 52° and 60°) as the abutments cleared in the primary predicate device K231127 and reference device K240609. The range of gingival heights of the subject device abutments (1.5 mm – 3.0 mm) is substantially equivalent to that of the abutments cleared in K231127 (gingival heights 2 mm, 3 mm) and the reference device K240609 (gingival heights range 1.5mm – 2.5mm).

The subject device implants, abutments, and abutment screws are provided sterile to the end user by means of gamma irradiation; this is the same sterilization method as used for the primary predicate device K231127 and the reference device K240609. All subject device components are packaged in a polyethylene terephthalate blister pack with a Tyvek cover and the appropriate label. These are the same packaging materials for the blister pack, and the same sealing methods as those used for the primary predicate device K231127. The sterile barrier shelf life of 4 years for the subject device is leveraged from the primary predicate K231127.

The risks associated with the subject device implant and abutment designs are mitigated by mechanical testing and an engineering rationale provided in the *Bench Testing* attachment to this submission. The mechanical testing data demonstrate that the subject device implants in combination with the subject device angled abutments have sufficient strength for their intended use.

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 the same or similar materials. The subject device, the primary predicate device and the reference devices encompass the same range of physical dimensions, are packaged in similar materials and are terminally sterilized using similar sterilization methods. The data included in this submission demonstrates substantial equivalence to the primary predicate device and reference devices listed above.

Table of Substantial Equivalence

Comparison	Subject Device	Primary Predicate	Reference Device	Reference Device	Reference Device
	K251129 **S.I.N. Tapered Pro Conical Zygoma Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**	**K231127** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**	**K240609** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**	**K240187** **Tapered Pro Conical Implant System** **BioHorizons Implant Systems, Inc.**	**K232099** **Neodent Implant System – GM Zygoma Implant System** **JJGC Indústria e Comércio de Materiais Dentários S.A.**
Indications for Use Statement	Pro Zygoma dental implants are intended for placement in the maxillary arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae. The Pro Zygoma dental implants may be used with single-stage or two-stage procedures and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	S.I.N. Dental Implant System Zygomatic implants are intended for placement in the maxillary arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System Zygomatic implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	S.I.N. Dental Implant System Zygomatic implants are intended for placement in the maxillary arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System Zygomatic implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	BioHorizons Tapered Pro Conical dental implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. These dental implants may be restored immediately (1) with a temporary prosthesis that is not in functional occlusion or (2) when splinted together for multiple tooth replacement or when stabilized with an overdenture supported by multiple implants. BioHorizons Tapered Short Conical dental implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. These dental implants must be restored using delayed loading, for single tooth replacement, or may be used with a terminal or intermediate abutment for fixed or removable bridgework or for overdentures. Tapered Short Conical implants should be used only when there is not enough space for a longer implant. If the ratio of crown length to implant length is unfavorable, the biomechanical risk factors have to be considered and appropriate measures have to be taken by the dental professional. BioHorizons conical dental prosthetic components connected to the endosseous dental implants are intended for use as an aid in prosthetic rehabilitations of the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed abutments for use with Conical CAD/CAM Ti Blanks and Ti Bases are to be sent to a BioHorizons validated milling center for manufacture.	Indications for Use for Zygoma-S GM Implant: Zygomatic implants are indicated for intraoral surgical procedures in the zygoma region in cases of severe maxilla bone resorption, to restore the patient's chewing function and aesthetics. Zygomatic Implants may be used in one or two-stage procedures, multiple unit restorations, and immediate loading when there is primary stability and adequate occlusal load. Indications for Use for GM Mini Conical Abutment 52° and 45°: Product indicated for surgical procedures in zygomatic bones, making possible the rehabilitation with screw-retained abutments over the implant, thus restoring the chewing function. It may be used in one- or two-stage procedures, multiple unit restorations, and immediate loading when there is primary stability and adequate occlusal load. Multiple rehabilitations may be splinted rigidly. Indications for Use for Coping for Removable Prosthesis: The product, when used with non-zygomatic implants, 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 multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted. When used with zygomatic implants, the product is indicated for surgical procedure only in upper jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used in two-stage procedures (delayed loading protocol) and for multiple unit restorations. Multiple rehabilitations may be splinted rigidly.

Table of Substantial Equivalence (cont.)

Comparison	Subject Device	Primary Predicate	Reference Device	Reference Device	Reference Device
	K251129 **S.I.N. Tapered Pro Conical Zygoma Implant System** **S.I.N. Implant System LTDA**	**K231127** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**	**K240609** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**	**K240187** **Tapered Pro Conical Implant System** **BioHorizons Implant Systems, Inc.**	**K232099** **Neodent Implant System – GM Zygoma Implant System** **JJGC Indústria e Comércio de Materiais Dentários S.A.**
Reason for Predicate/Reference Devices	Not applicable	Indications for Use; implant design; abutment design; materials, manufacturing, sterilization; shelf-life	Indications for Use; implant design; abutment design; materials, manufacturing, sterilization; shelf-life	Prosthetic interface connection; Implant endosseous surface treatment	Implant design (diameter); indications for use
Product Codes	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	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	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible
Implant Designs					
Implant types	**Pro Zygoma**: Zygomatic	Zygomatic	Zygomatic	Conventional	Zygomatic
Prosthetic Interface Connections	Deep conical with 6 anti-rotation cams at the base of the connection	Morse taper, 16°	Morse taper, 16°	Deep conical with 6 anti-rotation cams at the base of the connection	Internal GM prosthetic interface
Prosthetic Connection Diameter	3.0mm (Regular)	2.72mm	2.72mm	2.8mm (Narrow) 3.0mm (Regular)	*Not stated in 510(k) Summary*
Body Diameter	**Pro Zygoma**: 3.8 and 4.2mm	4.0mm (full length)	4.0mm (full length)	3.3mm; 3.8mm; 4.2mm; 4.6mm; 5.2mm	3.5mm, 3.75mm
Platform Diameter (outer diameter at implant platform)	**Pro Zygoma**: 3.8 and 4.2mm	4.0mm	4.0mm	3.4mm, 3.4mm, 3.8mm, 4.7mm, 4.8mm	4.3mm
Platform-to-Implant Axis Angulation	0° (Platform 90° to implant long axis)	0° (Platform 90° to implant long axis)	0° (Platform 90° to implant long axis)	0° (Platform 90° to implant long axis)	*Not stated in 510(k) Summary*
Lengths	**Pro Zygoma**: 30 mm – 60 mm 2.5 mm increments	30 mm – 60 mm 2.5 mm increments	30 mm – 60 mm 2.5 mm increments	7.5mm; 9.0mm; 10.5mm; 12.0mm; 15mm; 18mm	30mm, 35mm, 37.5mm, 40mm, 42.5mm, 45mm, 47.5mm, 50mm, 52.5mm, 55mm
Threaded Diameter and Threaded Lengths	**Pro Zygoma**: Thread diameter: 3.8 and 4.2mm Thread length: 16.8mm, starts at apex extends coronally	Thread diameter: 4.0 mm Thread length: 17 mm, starts at apex extends coronally	Thread diameter: 4.0 mm Thread length: 17 mm, starts at apex extends coronally	Thread diameter: 3.3mm, 3.8mm, 4.2mm, 4.6mm, 5.2mm Thread length: Matches implant length (7.5mm, 9.0mm, 10.5mm, 12.0mm, 15mm, 18mm	Thread diameter: 3.5mm, 3.75mm Thread length: 15mm
Implant Material	Ti-6Al-4V alloy	Unalloyed titanium, ASTM F67	Unalloyed titanium, ASTM F67	Ti-6Al-4V alloy	Grade 4 CP titanium (ASTM F67)
Implant Endosseous Surface	Resorbable Blast Texture (RBT), blasted with hydroxyapatite	Acid-etched and HA^{nano}	Acid-etched and HA^{nano}	Resorbable Blast Texture (RBT), blasted with hydroxyapatite	Sand blasted, acid etched NeoPoros surface

Table of Substantial Equivalence (cont.)

Comparison	Subject Device	Primary Predicate	Reference Device	Reference Device	Reference Device
	K251129 **S.I.N. Tapered Pro Conical Zygoma Implant System** **S.I.N. Implant System LTDA**	**K231127** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**	**K240609** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante Nacional S.A.**	**K240187** **Tapered Pro Conical Implant System** **BioHorizons Implant Systems, Inc.**	**K232099** **Neodent Implant System – GM Zygoma Implant System** **JJGC Indústria e Comércio de Materiais Dentários S.A.**
Abutments					
Abutment Designs	**Pro Conical Angled Multi-unit Abutments** Connection: Conical 15° Prosthetic Platform Ø: 4.8mm Gingival Height: 1.5, 2.0, 2.5, 3.0mm Angulation: 45°, 52°, 60°	**Abutment Mini Angled Morse Taper 45°** Connection: Morse taper 16° Prosthetic Platform Ø: 4.8 mm Gingival Height: 2 mm and 3 mm Angulation: 45°	**Abutment Mini Angled Morse Taper 52°, 60°** Connection: Morse taper 16° Prosthetic Platform Ø: 4.8 mm Gingival Height: 1.5, 2, 2.5 mm Angulation: 52°, 60°	Conical Multi-unit Abutments: Connection: Conical 15° Prosthetic Platform Ø: 4.8mm Gingival Height: 2.0, 3.0, 4.0mm Angulation: 0°, 17°, 30°	Connection: Internal GM prosthetic interface Gingival Height: 1.5mm, 2.5mm Angulation: 45°, 52°
Prosthesis Attachment	Screw-retained, multi-unit	Screw-retained, multi-unit	Screw-retained, multi-unit	Screw-retained; multi-unit	*Not stated in 510(k) Summary*
Abutment Material	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136
Abutment Screw Material	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	*Not stated in 510(k) Summary*
How Provided					
Implants	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation
Abutments	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by ethylene oxide
Abutment Screws	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	*Not stated in 510(k) Summary*