S.I.N. Implant System LTDA
Denise Domiciano
Quality and Regulatory Manager
Rua Soldado Ocimar Guimarães da Silva, 421
Sao Paulo, SP 03348060
BRAZIL

September 26, 2025

Re: K251262
Trade/Device Name: S.I.N. Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 15, 2025
Received: August 26, 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)*
K251262

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-stages urgical 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.

The Abutment Mini Angled Morse 45º is intended for use with the S.I.N. Dental Implant System Zygomatic implants. 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.

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
K251262

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

September 26th, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name	S.I.N. – Implant System LTDA. Rua Soldado Ocimar Guimarães da Silva, 421, São Paulo, São Paulo 03348-060 Brazil Telephone +55-11-93257-9157
Official Contact	Denise Domiciano, Quality and Regulatory Manager
Representative	S.I.N. Implant System LTDA. Rua Soldado Ocimar Guimarães da Silva, 421, São Paulo, São Paulo 03348-060 Brazil Telephone: +55-11-93257-9157 Denise Domiciano, Quality and Regulatory Affairs Manager Email regulatorios.matriz@sinimplantsystem.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	S.I.N. Dental Implant System
Common Names	Endosseous dental implant
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code	DZE
Secondary Product Code	NHA
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1 B (Dental Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate Device

K222231, S.I.N. Dental Implant System, S.I.N. - Sistema de Implante Nacional S.A.

Reference Predicate Devices

K231127, S.I.N. Dental Implant System, S.I.N. - Implant System LTDA

K193096, S.I.N. Dental Implant System, S.I.N. - Implant System LTDA; and

K213672, Biomet 3i LLC.

INDICATIONS FOR USE STATEMENT

S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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

The Abutment Mini Angled Morse 45º is intended for use with the S.I.N. Dental Implant System Zygomatic implants. 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.

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 K222231, K231127, and K170392.

This submission includes dental implants Epikut S with a Morse taper (MT) abutment interface and an acid-etched endosseous surface, and Epikut S Plus implants with an endosseous surface produced by acid- etching followed by application of a hydroxyapatite coating (HA^{nano}) and the same described conection. The implant design and endosseous surfaces are nearly identical to the Epikut S and Epikut S Plus implants cleared in K222231, with the exception of the additional body/platform diameter (6.0 /5.2 mm) with lengths of 8.5, 10, 11.5, 13.

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

Implant Lines	Body Ø, mm	Platform Ø, mm	Lengths, mm
Epikut S **Epikut S Plus**	6.0	5.2	8.5, 10, 11.5, 13

This submission includes Abutment Mini Angled Morse 45° in sizes from 1.5, 2.0, 2.5 with a 16° Morse taper connection mating abutments for screw retained, multi-unit prostheses and a prosthetic platform diameter of 4.8 mm, that is for exclusively use with cleared Zygomatic Plus implant. The corresponding abutment screw is PFMAAM 16A.

This submission includes Interface abutment MT 16° prosthetic components for fabrication of patient-specific abutments that are compatible with implants from S.I.N. Dental Implant System. Subject device Interface Abutments are two-piece abutments for which the second part (or top half) is the ceramic superstructure. The second part is designed and manufactured using CAD-CAM techniques. The titanium component of the Interface Abutments Morse Taper has a cementable platform diameter of 3.5mm, 4.5mm, or 5.5mm, cementable post-height of 4.0mm or 6.0mm, and a gingival height built into the titanium base component from 0.5mm to 4.0mm. The two pieces of the Ti-Base are bonded using Panavia Universal Dual-Cure Cement (K150704), as referenced in K190936. These abutments are used with a fixation screw PFMT 02A.

After scanning the intraoral area, the S.I.N.-validated milling center will receive the STL file and design the coping/superstructure using computer software (CAD) according to the design parameters below and the space available.

Design parameters for all Interface CAD-CAM Abutments superstructure are:
Minimum wall thickness – 0.5 mm
Minimum abutment 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
Maximum allowable abutment Post Height – 6 mm
Total abutment height – 10mm
Abutment diameter – depends on available space (for the patient)
By definition, the abutment post height is considered by FDA to be the "stump" portion above the gingival collar, to which the restorations attach.

PERFORMANCE DATA

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 K222231, K231127 and K193096).

bacterial endotoxin testing (referenced from K222231) 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 products on a quarterly basis to demonstrate all sterile products meet a limit of $\leq$ 20 EU/device.

Shelf-life testing (referenced from K222231) includes 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 reference device, K222231 to support biocompatibility of the subject device.

Referenced from K222231, characterization of the Hanano hydroxyapatite coating 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.

Referenced from K193096, moist heat sterilization for subject devices Interface CAD-CAM needs to be sterilized 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 K222231, 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 K222231 demonstrated that the subject device implants, in combination with compatible previously-cleared abutments, do not create a new worst-case construct, and for the subject device abutments with an angulation of 45° the previous mechanical testing from K222231 is applicable and for exclusive use to the device Zygomatic Plus implants do not create a new worst-case construct in this indication for use.

No clinical data was included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The primary predicate device K222231 is in support of substantial equivalence for the implant designs, Indications for Use statement, materials, manufacturing, and sterilization. The reference predicate device K213672 is for the implant body diameter 6.0. The reference predicate K231127 is in support of substantial equivalence of the abutment mini angle 45° for use exclusively with Zygomatic Plus implants, and the reference predicate K193096 is in support of substantial equivalence of the Interface Abutment MT 16° 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 K211921, K222231, K200992, and K170392. The IFUS for the subject device also includes identical language to that included in K231127 regarding abutment mini angle 45° for use exclusively with Zygomatic Plus implants

Differences between the IFUS for the subject device and the predicate devices include language in K222231 regarding long length implants are not relevant to the subject device.
Differences between the IFUS for the subject device and the reference predicate devices K213672 include language regarding abutment loading and design also are not relevant to the subject device.

Subject Device Dental Implants

The subject device Epikut S and Epikut S Plus implants have nearly identical designs, Morse taper connection (except for the body diameter of 6.0 mm), and manufacturing as used for the Epikut S and Epikut S Plus implants cleared in K222231. The subject device Epikut S and Epikut S Plus implants have the same 16° internal Morse taper abutment connection and are provided in the same range of lengths as the implants cleared in K222231; the subject implants are provided in an additional body diameter of 6.0 mm, which is within the range of the implant sizes cleared in K213672.

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. The subject device Epikut S Plus implants have the same acid-etched and HA^{nano} endosseous surface treatment as used for implants cleared in K222231 and K193096.

All subject device implants, abutments and prosthetic components (screws) are provided sterile by gamma irradiation. The subject devices have the same sterilization method, packaging, and sterile barrier shelf life as devices cleared in K222231, K231127, and K193096.

Subject Device Abutments

The subject devices Abutment Mini Angled Morse 45° are substantially equivalent to the Abutment Mini Angled 45°cleared in K231127 in terms of similar designs, the same prosthetic platform diameter, almost the same range of gingival heights, identical material and the angulation of 45°. The subject device abutments with an angulation of 45° are intended to be used only with the Zygomatic Plus implants.

The reference predicate device K231127 is for support of substantial equivalence of the 45° abutment angulation design, same Morse taper connection and the same abutment material (Ti-6Al-4V alloy). The risks associated with use of the subject device angled abutments in combination with the subject device Zygomatic Plus implants are mitigated by the mechanical testing according to ISO 14801 presented on K222231.

Subject Device Interface abutment

The subject device Interface Abutments MT 16° and the respective screw PFMT 02A are abutment-level prosthetic components that are substantially equivalent to corresponding prosthetic components used with Interface Abutments MT 16° and correspondent screws cleared in K193096 (Mose taper). The subject device Interface Abutments MT 16° have almost the same sizes or ranges of sizes for platform diameter, prosthetic platform diameter, and gingival height as the predicate device K193096 Interface Abutments

CONCLUSION

The subject device, the primary predicate device, and the reference 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 reference 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 demonstrates substantial equivalence to the predicate devices listed above.

Table of Substantial Equivalence

	Subject Device	Primary Predicate Device	Reference Predicate	Reference Predicate	Reference Predicate
	S.I.N. Dental Implant System **S.I.N. - Implant System LTDA**	**K222231** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante S.A.**	**K213672** **Biomet 3i LLC** **T3 Pro Dental Implants**	**K231127** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante S.A.**	**K193096** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante 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. 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. The Abutment Mini Angled Morse 45º is intended for use with the S.I.N. Dental Implant System Zygomatic implants. 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 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 T3 Pro Dental Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures The T3 Pro Implants may also utilize immediate loading for these indications. The T3 Pro Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. The T3 Pro Dental Implants achieve their intended purpose based upon their macro design features, which maximize primary stability at time of placement.	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 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.
Reason for Predicate Device	Not applicable	Implant design; materials; manufacturing; sterilization	Implant design; materials; sterilization	Abutment designs; materials; manufacturing; sterilization	Abutment designs; materials; manufacturing; sterilization
Product Codes	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

	Subject Device	Primary Predicate Device	Reference Predicate	Reference Predicate	Reference Predicate
	S.I.N. Dental Implant System **S.I.N. - Implant System LTDA**	**K222231** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante S.A.**	**K213672** **Biomet 3i LLC** **T3 Pro Dental Implants**	**K231127** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante S.A.**	**K193096** **S.I.N. Dental Implant System** **S.I.N. – Sistema de Implante S.A.**
Implant Designs					
Prosthetic Interface Connections	Morse taper (MT, 16°)	Morse taper (MT, 16°)	Internal Hex Mating Components: Biomet 3i Internal Connection Restorative Components	Morse taper (MT, 16°)	External hex (HE), Internal hex (HI), Morse taper (CM)
Body/Platform Diameters, mm Lengths, mm Interface	**Epikut S** 6.0/5.2 8.5 – 13, Morse taper interface (MT,16°)	**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 (MT, 16°)	**T3 Pro** Diameter Range Ø3.25mm, 4mm, 5mm and **6mm** Seating Platform Diameter Ø3.4mm, 4.1mm, 5mm and **6mm** Ø3.25: 8.5mm, 10mm, 11.5mm, 13mm and 15mm Ø4.0: 8.5mm, 10mm, 11.5mm, 13mm and 15mm Ø5.0: 8.5mm, 10mm, 11.5mm, 13mm and 15mm **Ø6.0: 8.5mm, 10mm, 11.5mm, 13mm and 15mm** Platform Switched and Non-Platform Switched Implants Tapered Only Internal Hex Straight Shortened Collar Design Subject Tapered Implant: 23° thread & 0.8mm pitch		
Body/Platform Diameters, mm Lengths, mm Interface	**Epikut S Plus** 6.0/5.2 8.5–13 Morse taper interface (MT, 16°)	**Epikut S Plus** 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°)			
Implant Material	All implants: unalloyed titanium, ASTM F67	All implants: unalloyed titanium, ASTM F67	*Commercially Pure Titanium (CP4) Per ASTM F67*	Unalloyed titanium, ASTM F67	All implants: unalloyed titanium, ASTM F67
Implant Endosseous Surface	All implants: acid-etched; HA^{nano} applied to the Epikut S Plus implants	All implants: acid-etched; HA^{nano} applied to the Epikut S Plus implants	• Grit Blasted with Calcium Phosphate (CaP) • Dual-acid Etching (OSSEOTITE®) • Without DCD **Anodized Platform Surface Color:** Purple, Blue, Yellow and Green	Acid-etched and HAnano	All implants: acid-etched + HAnano applied, *except* Tryon Conic HE acid-etch only
Conventional Abutment Designs	**Abutment Mini Angled Morse Taper 45°** Morse taper interface (MT, 16°) Prosthetic Platform Ø: 4.8 Gingival Height: 1.5 mm – 2.5 mm Angulation: 45° (Exclusively for use with Zygomatic Plus implants)			**Abutment Mini Angled Morse Taper 45°** Morse taper interface (CM, 16°) Prosthetic Platform Ø: 4.8 mm Gingival Height: 2 mm and 3 mm Angulation: 45°	**Universal Cemented Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/3.3 mm Gingival height: 2, 3, 4 mm Titanium alloy, ASTM F136 **Cemented Abutment SIT** Morse taper interface (CM) Platform/Prosthetic platform Ø: 3.3/3.3, 4.5/4.5 mm Gingival height: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm Titanium alloy, ASTM F136

					Healing Abutment External hex interface (HE) Platform Ø: 3.65 mm Prosthetic platform Ø: n/a Gingival height: 2, 4, 6 mm Titanium alloy, ASTM F136 **Provisional Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/3.6 mm Gingival height: 1.2 mm Titanium alloy, ASTM F136 **UCLA-type Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/4.0 mm Gingival height: 1 mm Cobalt-chromium alloy, ASTM F1537 **UCLA-type Abutment** Internal hex interface (HI) Platform/Prosthetic platform Ø: 3.8/4.5, 4.5/4.7 mm Gingival heights: 0.5 mm and 1 mm Cobalt-chromium alloy, ASTM F1537 **Micro-Mini Abutment** External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/3.5 mm Gingival heights: 2, 3, 4 mm Titanium alloy, ASTM F136 **Abutment Protectors** For abutments with HE, HI, CM interface Platform Ø: 3.65 mm, 4.8 mm Maximum Ø: 3.65, 4.5, 6 mm Titanium alloy, ASTM F136
Interface Morse Taper Abutments	Morse taper interface (MT, 16°) Prosthetic platform Ø: 3.5, 4.5, 5.5 mm. Gingival height: 0.5, 1.0, 2.0, 3.0 and 4.0 mm Angulation: 0º				**Various Interface Abutment Designs** Morse taper interface (CM) Platform/Prosthetic platform Ø: 3.5/3.5, 3.5/4.25 mm Gingival height: 0.5, 0.8, 2, 3 mm **Fits Conical Abutments** Platform Ø: matches compatible Conical Abutments Prosthetic platform Ø: 5.5 mm Gingival height: 0.35 mm **For Strong SW CM and Strong SW CM Plus Implants** Morse taper interface (CM) Platform/Prosthetic platform Ø: 3.5/3.5, 3.5/4.25 mm Gingival height: 0.5, 0.8, 2, 3 mm **For Mini Abutments** Platform Ø: matches Mini Abutments Prosthetic platform Ø: 5.5 mm Gingival height: 0.35 mm **For Micro Mini Abutments** Platform Ø: matches Micro Mini Abutments Prosthetic platform Ø: 3.8 mm Gingival height: 0.5 mm
Abutment Materials	Titanium alloy, ASTM F136 and Zirconia			Titanium alloy, ASTM F136	Titanium alloy, ASTM F136

	Y-TZP, conforming to ISO13356 (superstrutures)				Cobalt-chromium alloy, ASTM F1537 Zirconia (Y-TZP), ISO 13356 (superstructures)
How Provided					
Implants	Sterile by gamma irradiation	Sterile by gamma irradiation	Supplied Sterile (Gamma radiation)	All sterile by gamma irradiation	All sterile by gamma irradiation
Abutments	Sterile by gamma irradiation			All sterile by gamma irradiation	All sterile by gamma irradiation, *except:* Provisional and UCLA-type abutments; CAD-CAM abutments in cobalt-chromium alloy Non-sterile components to be moist heat sterilized by end user
Usage – All Components	Single patient, single use	Single patient, single use	*Not stated in 510(k) Summary*	Single patient, single use	Single patient, single use