



October 17, 2025

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

Re: K252266  
Trade/Device Name: S.I.N. Dental Implant System  
Regulation Number: 21 CFR 872.3630  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: Class II  
Product Code: NHA  
Dated: July 18, 2025  
Received: July 21, 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](mailto: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

## Indications for Use

510(k) Number (if known)  
K252266

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 may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

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.

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**510(k) Summary****S.I.N. Implant System LTDA****S.I.N Dental Implant System**October 17<sup>th</sup>, 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 +55-11-21693000 ext 3236
Official Contact	Denise Domiciano, Quality and Regulatory Affairs Manager
Representative/Consultant	S.I.N. Implant System LTDA Rua Soldado Ocimar Guimarães da Silva, 421 São Paulo, São Paulo 03348-060 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 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
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  
K193096, S.I.N. Dental Implant System, S.I.N. Implant System LTDA

## Additional Devices

K200992, 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

#### 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 implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

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

#### SUBJECT DEVICE DESCRIPTION

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

This submission adds Interface Abutments and Healing Abutments to the S.I.N. Dental Implant System. The subject device Interface abutments are provided with MT 16° and CM11.5° connection compatible with the S.I.N. Dental implants.

#### Subject Device Interface Abutments

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 has a cementable platform diameter of 3.5mm, 4.0mm, 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 4.0 mm. The two pieces of the Ti-Base are bonded using Panavia Universal Dual-Cure Cement (K150704), as referenced in K190936.

All subject devices are provided only in straight designs, with no pre-angled conventional abutments or pre-angled CAD-CAM abutments. No subject device abutment is to be customized to create an angled abutment or to correct for angulation, and no superstructure for use with any subject device Interface abutment (CAD-CAM) is to be fabricated to create a final abutment with angulation or to correct for angulation. Therefore, this model has a slight design difference to improve screw insertion and removal. It was purposely designed to optimize fixation and removal of the screw connection. This new presentation allows screw fixation even in cases of anterior aesthetic rehabilitation, avoiding the need to create screw access holes in the sublingual phase. However, it is confirmed that all implant-abutment interfaces are intended exclusively for straight configurations and are not indicated for any angled model. These minor differences in the exact dimensions of the subject device interface abutment as compared to the predicate device and reference devices do not impact safety, effectiveness, or substantial equivalence.

The subject device interface abutments with the CM11.5° interface are compatible with implants cleared in K200992, K221453, K211921 and K170392 in terms of abutment-implant connection. The subject device with the MT16° interface is compatible with implants cleared in K222231, K193096 and K170392 in terms of abutment-implant connection.

The design parameters for the CAD-CAM fabrication of patient-specific abutments from CAD/CAM Abutments are the same for the 11.5° CM implant connection and the MT 16° implant connection. The design limit parameters are:

Minimum wall thickness – 0.5 mm

Minimum abutment post height for single-unit restoration – 4.0 mm

Maximum angle – 0°. Straight only

Maximum angle for screw insertion/removal – 20°

Maximum gingival height – 5.0mm

Minimum Gingival Height – 0.5 mm

Maximum allowable abutment Post Height – 6 mm

Total Abutment Height – 10mm

Abutment diameter – depends on available space (for the particular 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.

All subject device Interface Abutments are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 and the same zirconia that is specified for superstructures in K190396, and are to be used with subject abutment screws. All subject devices are provided sterile. All Interface abutments are provided sterile by gamma irradiation; the same sterilization method used in predicate device K190396 and in the additional devices K200992 and K170392.

All Interface abutments manufactured from titanium alloy are anodized using a standard anodization process is identical to the anodization process used on abutments cleared in K190396.

The subject device abutments screws are to be used with Interface Abutments present in this submission and they are substantially equivalent to material (titanium alloy) and designs to abutments screws cleared in K170392.

#### Subject Device Healing Caps

The subject device Healing Cap is substantially equivalent to the corresponding design Healing Cap cleared in K170392. The subject device healing cap is designed for the healing period between implant placement and final abutment placement and is not intended to support a temporary prosthesis.

All Healing Caps are provided sterile by gamma irradiation; the same sterilization method used in predicate device K170392 and additional predicate device K200992.

All subject device components are provided sterile by gamma irradiation, the same sterilization method used in K190396, K170932 and K200992.

#### PERFORMANCE DATA

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

- moist heat sterilization for subject devices provided non-sterile to the end user to a sterility assurance level of 10<sup>-6</sup> by the overkill method according to ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO TIR 17665-2.
- biocompatibility testing according to ISO 10993-5 (cytotoxicity) for the abutment material ASTM F136 (Provided in K170398).
- Referenced from K251262, MR Conditional labeling for the subject devices has been leveraged to support FDA requirements. The 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 2213 (magnetically induced torque), ASTM F2182 (RF induced heating), and ASTM F2119 (image artifact), and the FDA guidance document *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* (issued May 2021); and
- Engineering analysis provided in this submission to demonstrate that the subject device abutments, in combination with compatible previously cleared dental implants, do not create a new worst-case construct, and that previous mechanical testing conducted according to ISO 14801 (submitted in K200992) is applicable to the subject device abutments.

No clinical data was included in this submission.

#### EQUIVALENCE TO MARKETED DEVICES

The subject devices are substantially equivalent in indications and design principles to the primary predicate device and the additional predicate 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 additional devices.

The primary predicate device K193096 is in support of substantial equivalence of the Indications for Use and components designs, materials, manufacturing, sterilization, and compatible implants, to the subject device

Interface Abutment. The additional predicate device devices K200992 and K170392 are in support of substantial equivalence of the Indications for Use, abutment designs, materials, manufacturing, sterilization, and compatible implants to the subject device Healing Cap.

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 K193096 and K170392. The IFUS for the subject device also includes language concerning CAD-CAM abutments and validated milling centers that are nearly identical to that included in K193096 and K170392.

For subject device Interface abutments, the limits of fabrication for the required superstructure are the same as the limits of fabrication for the superstructure for K190396. The material recommended for the fabrication of the superstructure of the subject device CAD-CAM abutments also in the same zirconia that is specified for superstructures in K190396.

## CONCLUSION

The subject device, the primary predicate device, and the additional predicate devices have the same intended use, have similar technological characteristics, and are made of identical materials. The subject devices, 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**

**Table of Substantial Equivalence**

	<b>Subject Device</b>	<b>Primary Predicate</b>	<b>Additional Predicate</b>	<b>Additional Predicate</b>
<b>Comparison</b>	<p><b>S.I.N. Dental Implant System</b></p> <p><b>S.I.N. Dental Implant System</b></p>	<p><b>K193096</b></p> <p><b>S.I.N. Dental Implant System</b></p> <p><b>S.I.N. Dental Implant System</b></p>	<p><b>K170392</b></p> <p><b>S.I.N. Dental Implant System</b></p> <p><b>S.I.N. Dental Implant System</b></p>	<p><b>K200992</b></p> <p><b>S.I.N. Dental Implant System</b></p> <p><b>S.I.N. Dental Implant System</b></p>
<b>Indications for Use</b>	<p>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 implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.</p> <p>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.</p>	<p>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 implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.</p> <p>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.</p>	<p>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.</p>	<p>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.</p>
<b>Reason for Predicate / Reference Devices</b>	Not Applicable	Abutments designs, Intended Use, Abutment material and abutment screw material, Sterilization and Usage.	Abutments designs, Intended Use, Abutment material and abutment screw material, Sterilization and Usage.	Abutment dimension, Intended Use, Abutment screw material, Sterilization and Usage.
<b>Product Codes</b>	NHA	DZE, NHA	DZE, NHA	DZE, NHA
<b>Intended Use</b>	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
<b>CAD-CAM Abutments Designs</b>				
<b>Interface Abutments</b>	<p><b>For Strong SW CM, Strong SW CM Plus, Epikut S and Epikut S Plus Implants:</b> Morse taper interface (MT16) Platform/Prosthetic platform Ø: 3.5, 4.0, 4.5 and 5.5 mm Gingival Height: 0.5, 1.0, 2.0, 3.0 and 4.0 mm Titanium Alloy, ASTM F136</p>	<p><b>Fit Conical Abutments:</b> Morse taper interface (MT) Platform/Prosthetic platform Ø: 3.5/3.5, 3.5/4.25 mm Gingival Height: 0.5, 0.8, 2.3 mm Titanium Alloy, ASTM F136</p> <p><b>For Strong SW CM and Strong SW CM Plus Implants:</b> Morse taper interface (CM16) Platform/Prosthetic platform Ø: 3.5/3.5, 3.5/4.25 mm Gingival height: 0.5, 0.8, 2, 3 mm Titanium alloy, ASTM F136</p> <p><b>For Unitite CM Implants:</b> Morse taper interface (CM) Platform/Prosthetic platform Ø:</p>		

		<p>3.5/3.5, 3.5/4.25 mm Gingival height: 0.5, 0.8, 2, 3 mm Titanium alloy, ASTM F136</p> <p><b>For Strong SW HE, Strong SW HE Plus, and Tryon Implants:</b> External hex interface (HE) Platform/Prosthetic platform Ø: 3.4/4.1, 3.65/4.1, 4.1/4.3, 4.1/5.0 mm Gingival height: 0.6, 1.0 mm Cobalt-chromium alloy, ASTM F1537 and Titanium alloy, ASTM F136</p> <p><b>For Strong SW HI and Strong SW HI Plus Implants:</b> Internal hex interface (HI) Platform/Prosthetic platform Ø: 3.8/4.1, 3.8/4.3 mm Gingival height: 0.5 mm Cobalt-chromium alloy, ASTM F1537 and Titanium alloy, ASTM F136</p> <p><b>For Mini Abutments:</b> Platform Ø: matches Mini Abutments Prosthetic platform Ø: 5.5 mm Gingival height: 0.35 mm Cobalt-chromium alloy, ASTM F1537 and Titanium alloy, ASTM F136</p> <p><b>For Micro Mini Abutments:</b> Platform Ø: matches Micro Mini Abutments Prosthetic platform Ø: 3.8 mm Gingival height: 0.5 mm Cobalt-chromium alloy, ASTM F1537 and Titanium alloy, ASTM F136</p> <p><b>For Strong SW HE, Strong SW HE Plus, and Tryon Implants:</b> External hex interface (HE) Platform/Prosthetic platform Ø: 3.65/4.1, 4.1/4.3 mm Gingival height: 1.0 mm Cobalt-chromium alloy, ASTM F1537 and Titanium alloy, ASTM F136</p>		
<p>Healing Cap</p>	<p><b>For Strong SW CM, Strong SW CM Plus, Epikut S and Epikut S Plus Implants:</b> Morse taper interface (MT16) Coronal Ø: 5, 5 mm Gingival Height: 6.0 mm Titanium Alloy, ASTM F136</p>		<p><b>For Strong SW CM Implants:</b> Morse taper interface (MT16) Coronal Ø: 3,5 and 4.5 mm Gingival Height: 2.0, 4.0 and 6.0 mm Titanium Alloy, ASTM F136</p> <p><b>For Unitite Slim Implants:</b> Morse taper interface (CM3) Coronal Ø: 3,3 mm Gingival Height: 1.5, 2.5, 3.5 and 4.5 mm Titanium Alloy, ASTM F136</p> <p><b>For Unitite Implants:</b> Morse taper interface (CM11.5) Coronal Ø: 3.3, 4.5 mm Gingival Height: 0.8, 1.5, 2.5, 3.5, 4.5 and 5.5 mm Titanium Alloy, ASTM F136</p>	<p><b>Healing Cap Morse / Healing Cap Morse Indexed</b> Morse taper interface (CM, 16°) Coronal Ø: 5, 8 mm Gingival Height: 4, 8 mm Non-indexed and indexed Titanium alloy ASTM F136 (interface to implant) PEEK (customizable portion)</p> <p><b>Healing Cap / Healing Cap Indexed</b> Morse taper interface (CM, 11.5°) Coronal Ø: 5, 8 mm Gingival Height: 4, 8 mm Non-indexed and indexed Titanium alloy ASTM F136 (interface to implant) PEEK (customizable portion)</p> <p><b>Healing Cap Compact /</b></p>

			<p><b>For Unitive Compact Implants:</b> Morse taper interface (CM4) Coronal Ø: 4.0 mm Gingival Height: 2.0, 4.0 and 6.0 mm Titanium Alloy, ASTM F136</p>	<p><b>Healing Cap Compact Indexed</b> Morse taper interface (CM, 4°) Coronal Ø: 5, 8 mm Gingival Height: 4, 8 mm Non-indexed and indexed Titanium alloy ASTM F136 (interface to implant) PEEK (customizable portion)</p> <p><b>Healing Cap Slim / Healing Cap Slim Indexed</b> Morse taper interface (CM, 3°) Coronal Ø: 5, 8 mm Gingival Height: 4, 8 mm Non-indexed and indexed Titanium alloy ASTM F136 (interface to implant) PEEK (customizable portion)</p> <p><b>Healing Cap HE / Healing Cap HE Indexed</b> External hex interface (HE) Platform Ø: 3.4, 3.5, 4.1, 5.0 mm Coronal Ø: 5, 8 mm Gingival Height: 6.8 mm Non-indexed and indexed Titanium alloy ASTM F136 (interface to implant) PEEK (customizable portion)</p> <p><b>Healing Cap HI / Healing Cap HI Indexed</b> External hex interface (HI) Platform Ø: 3.8, 4.5 mm Coronal Ø: 5, 8 mm Gingival Height: 6.8 mm Non-indexed and indexed Titanium alloy ASTM F136 (interface to implant) PEEK (customizable portion)</p>
Abutments Material	<p><b>Interface Abutment</b> Titanium alloy, ASTM F136 Zirconia (Y-TZP), ISO 13356 (superstructures)</p> <p><b>Healing Cap:</b> Titanium alloy, ASTM F136</p>	<p><b>All Interface Abutment:</b> Titanium alloy, ASTM F136 Zirconia (Y-TZP), ISO 13356 (superstructures)</p>	<p><b>Healing Cap:</b> Titanium alloy, ASTM F136</p>	<p><b>Healing Cap:</b> Titanium alloy ASTM F136 (interface to implant) PEEK (customizable portion)</p>
Abutment Screw Material	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Not applicable.	Not applicable.
Abutments	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation	All sterile by gamma irradiation
Abutments Screws	<p><b>Interface Abutment</b> All sterile by gamma irradiation</p> <p><b>Healing Cap:</b> Not applicable.</p>	All sterile by gamma irradiation	Not applicable.	Not applicable.
Usage	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use