



December 18, 2025

SIMDA Co.,Ltd.
Cha Young Woo
Regulatory Affairs Manager
233, Hakgam dea-ro, Sasang-gu
Busan, 46986
REPUBLIC OF KOREA

Re: K252320
Trade/Device Name: SIMDA Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 18, 2025
Received: November 18, 2025

Dear Cha Young Woo:

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

Indications for Use

510(k) Number (if known)
K252320

Device Name

SIMDA Abutments

Indications for Use (Describe)

SIMDA Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

It is compatible with the following systems:

Pre-Milled Blank, Patient-specific abutment

Compatible System	Implant Body Diameter(mm)	Implant Platform
Astra OsseoSpeed® EV (K120414, K130999)	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4
Astra Tech Implant System (K101732) Astra Tech OsseoSpeed Astra Tech Fixture MicroMacro (New indication) (K024111)	3.0S, 3.5S, 4.0S, 4.5, 5.0, 5.0S	3.0(x-small), 3.5/4.0(small), 4.5/5.0(large)
BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8
Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB

Ti-Base abutment

Compatible System	Implant Body Diameter(mm)	Implant Platform
BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8
Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB

Multi-unit abutment

Compatible System	Implant Body Diameter(mm)	Implant Platform
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB

Multi-unit Abutment is only compatible with Straumann BLX Implant System.

All digitally designed abutments for use with SIMDA Abutments are intended to be sent to a SIMDA 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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K252320

510(k) Summary

Applicant

Name: SIMDA Co., Ltd.
 Address: 233, Hakgam dea-ro, Sasang-gu, Busan, South Korea
 Phone: +82 70 4256 2855
 Contact: Young Woo, Cha
 Email: Email: chassi0406@gmail.com
 Date Prepared: 12/17/2025

Subject Device

Trade Name: SIMDA Abutment
 Common Name: Endosseous dental implant abutment
 Classification Name: Abutment, Implant, Dental, Endosseous
 Product Code: NHA
 Panel: Dental
 Regulation Number: 21 CFR 872.3630
 Device Class: Class II

Primary	510(k)	Manufacturer(s)
SIMDA Abutment	K223663	SIMDA Co., Ltd.

Reference	510(k)	Manufacturer(s)
OsseoSpeed Profile EV	K130999	Dentsply Implants Manufacturing GmbH
OsseoSpeed Plus	K120414	Astra Tech AB
Astra Tech Fixture OsseoSpeed, Astra Tech Fixture MicroMacro (New Indication)	K024111	Astra Tech, Inc.
Astra Tech Implant System	K101732	Astra Tech AB
BioHorizons Laser-Lok 3.0 Implant System	K093321	BioHorizons Implant Systems, Inc.
BioHorizons Tapered Internal Implants	K143022	BioHorizons Implant Systems, Inc.
BioHorizons Tapered Internal Implant System	K071638	BioHorizons Implant Systems, Inc.
CP4 Osseotite Certain Dental Implants	K130949	Biomet 3i
Straumann BLX Implant System	K173961	Institut Straumann AG
Straumann BLX Line Extension – Implants, SRAs and Anatomic Abutments	K181703	Institut Straumann AG
Straumann BLX Ø3.5 mm Implants	K191256	Institut Straumann AG
URIS OMNI Narrow System & Prosthetic	K200817	Truabutment, Inc.
INCORIS ZI	K123664	Sirona Dental Systems GmbH
MALTA	K100756	3M Espe AG Dental Products

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Device Description

SIMDA Abutment is intended for use as an aid in prosthetic restoration. It consists of Pre-Milled Blank, Ti-Base, Multi-unit Abutment, Multi-unit Base. It has a pre-manufactured connection interface that fits directly to an endosseous dental implant.

Pre-milled Blank Design

This device is a patient-specific abutment composed of titanium alloy (Ti-6Al-4V ELI, ASTM F136) which is designed by a clinician or lab, and milled at a SIMDA validated milling center.

Pre-Milled Blank Design Limitation for Patient-specific abutment:

Design parameter (Patient-specific abutment)	Subject System Design Limit
Minimum and Maximum Gingival (Cuff) Height	0.5~5mm
Minimum and Maximum diameter at abutment/implant interface	Ø4.0~Ø8.0
Minimum and Maximum length of abutment	6~12mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4~8mm
Minimum wall thickness at abutment/implant interface	0.32 (Astra EV) 0.32 (Astra TX) 0.39 (BioHorizons) 0.4 (Biomet 3i) 0.42 (Straumann BLX)
Minimum and Maximum abutment angle	0~15° (Astra EV and Astra TX) 0~25° (BioHorizons, Biomet 3i, and Straumann BLX)

Pre-Milled Blank Design Limitation for Patient-specific abutment:

Astra OsseoSpeed EV, Astra Tech OsseoSpeed TX is minimum and maximum abutment angle 0~15 °

Ti-Base Abutment

Ti Base consists of a two-piece abutment, where the titanium base is a pre-manufactured titanium component that will be used to support a CAD/CAM-designed zirconia superstructure (the second part of the two-piece abutment) that composes the final abutment.

Ti Base are provided non-sterile therefore must be sterilized after the cementation of the patient-specified superstructure.

Raw material blanks

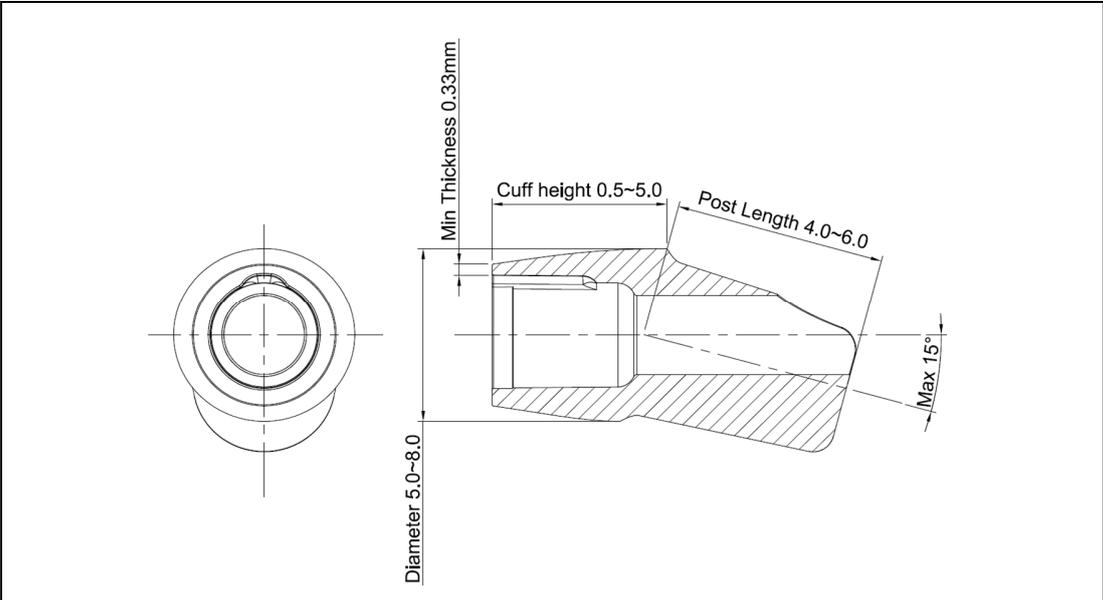
- InCoris Zi (ZrO2) by Sirona Dental Systems GmbH, L size blanks, cleared under K123664.

Cement

- RelyX Unicem 2Automix by 3M ESPE, cleared under K100756.

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Design Limitation for Zirconia superstructure:



Design Parameter	Limit (Min.~Max.)
Minimum and Maximum abutment angle	0~15
Minimum and Maximum Gingival (Cuff) Height	0.5~5.0
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4.0~6.0
Minimum and Maximum diameter at abutment/implant interface	5.0~8.0
Minimum wall thickness at abutment/implant interface	0.33

Multi-unit Abutment and Base

Multi-unit Abutment which are placed into the dental implant to provide support for the prosthetic restoration. The abutments are made of Titanium grade Ti-6Al-4V ELI (meets ASTM Standard F-136). The Multi-unit Abutment has a post height less than 4mm and are always combined with Multi-unit Base, increasing the post height to a minimum of 4.5mm.

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Indication for Use

SIMDA Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

It is compatible with the following systems:

Pre-Milled Blank, Patient-specific abutment

Compatible System	Implant Body Diameter(mm)	Implant Platform
Astra OsseoSpeed EV (K120414, K130999)	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4
Astra Tech Implant System (K101732) Astra Tech Fixture OsseoSpeed, Astra Tech Fixture MicroMacro (New Indication) (K024111)	3.0S, 3.5S, 4.0S, 4.5, 5.0, 5.0S	3.0(x-small), 3.5/4.0(small), 4.5/5.0(large)
BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8
Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB

Ti-Base

Compatible System	Implant Body Diameter(mm)	Implant Platform
BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8
Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB

Multi-unit abutment

Compatible System	Implant Body Diameter(mm)	Implant Platform
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB

Multi-unit Abutment is only compatible with Straumann BLX Implant System.

All digitally designed abutments for use with SIMDA Abutments are intended to be sent to a SIMDA validated milling center for manufacture.

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Primary Predicate / Reference devices:

The subject device is substantially equivalent to the following primary predicate and reference devices:

- Primary Predicate
 - SIMDA Abutment (K223663)

- Reference devices
 - OsseoSpeed Profile EV (K130999) by Dentsply Implants Manufacturing GmbH
 - OsseoSpeed Plus (K120414) by Astra Tech AB
 - Astra Tech Fixture OsseoSpeed, Astra Tech Fixture MicroMacro (New Indication) (K024111) by Astra Tech, Inc.
 - Astra Tech Implant System (K101732) by Astra Tech AB.
 - BioHorizons Laser-Lok 3.0 Implant System (K093321) by Biohorizons Implant Systems, Inc.
 - Biohorizons Tapered Internal Implant System (K143022) by Biohorizons Implant Systems, Inc.
 - Biohorizons Tapered Internal Implant System (K071638) by Biohorizons Implant Systems, Inc.
 - CP4 Osseotite Certain Dental Implants (K130949) by Biomet 3i
 - Straumann BLX Implant System (K173961) by Institut Straumann AG
 - Straumann BLX Line Extension - Implants, SRAs and Anatomic Abutments (K181703) by Institut Straumann AG
 - Straumann BLX Ø3.5 Mm Implants (K191256) by Institut Straumann AG
 - URIS OMNI Narrow System & Prosthetic (K200817) by TruAbutment Inc.
 - INCORIS ZI (K123664) by Sirona Dental Systems GmbH
 - MALTA (K100756) by 3M Espe AG Dental Products

Comparison between Primary predicates

- **Pre-Milled Blank**

Feature	Proposed Device SIMDA Abutment	Primary predicate SIMDA Abutment	SE discussion
Applicant	SIMDA Co., Ltd.	SIMDA Co., Ltd.	=
Part Name	Pre-Milled Blank	Pre-Milled Blank	=
510(K) No.	-	K223663	=
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)	Identical
Product Code	NHA	NHA	Identical
Screw and Abutment Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Identical
Indications For Use	SIMDA Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.	SIMDA Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.	The subject device is substantially equivalent in indications and design principles to the primary predicate device listed above. Provided tables are comparing

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Feature	Proposed Device SIMDA Abutment	Primary predicate SIMDA Abutment	SE discussion																																																	
	<p>It is compatible with the following systems:</p> <p>Pre-Milled Blank, Patient-specific abutment</p> <table border="1" data-bbox="280 528 719 1249"> <thead> <tr> <th>Compatible System</th> <th>Implant Body Diameter(mm)</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td>Astra OsseoSpeed EV (K120414, K130999)</td> <td>3.0, 3.6, 4.2, 4.8, 5.4</td> <td>3.0, 3.6, 4.2, 4.8, 5.4</td> </tr> <tr> <td>Astra Tech Implant System (K101732) Astra Tech Fixture OsseoSpeed Astra Tech Fixture MicroMacro (New indication) (K024111)</td> <td>3.0S, 3.5S, 4.0S, 4.5, 5.0, 5.0S</td> <td>3.0(x-small), 3.5/4.0(small), 4.5/5.0(large)</td> </tr> <tr> <td>BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> </tr> <tr> <td>Biomet 3i Certain® (K130949)</td> <td>3.25, 4.0, 5.0, 6.0</td> <td>3.25, 4.0, 5.0, 6.0</td> </tr> <tr> <td>Straumann BLX Implant (K173961, K181703, K191256)</td> <td>3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5</td> <td>RB, WB</td> </tr> </tbody> </table> <p>Ti-Base</p> <table border="1" data-bbox="280 1308 719 1711"> <thead> <tr> <th>Compatible System</th> <th>Implant Body Diameter(mm)</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td>BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> </tr> <tr> <td>Biomet 3i Certain® (K130949)</td> <td>3.25, 4.0, 5.0, 6.0</td> <td>3.25, 4.0, 5.0, 6.0</td> </tr> <tr> <td>Straumann BLX Implant (K173961, K181703, K191256)</td> <td>3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5</td> <td>RB, WB</td> </tr> </tbody> </table> <p>Multi-unit abutment</p> <table border="1" data-bbox="280 1769 719 1917"> <thead> <tr> <th>Compatible System</th> <th>Implant Body Diameter(mm)</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td>Straumann BLX Implant (K173961, K181703, K191256)</td> <td>3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5</td> <td>RB, WB</td> </tr> </tbody> </table> <p>Multi-unit Abutment is only compatible with Straumann BLX Implant System.</p>	Compatible System	Implant Body Diameter(mm)	Implant Platform	Astra OsseoSpeed EV (K120414, K130999)	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4	Astra Tech Implant System (K101732) Astra Tech Fixture OsseoSpeed Astra Tech Fixture MicroMacro (New indication) (K024111)	3.0S, 3.5S, 4.0S, 4.5, 5.0, 5.0S	3.0(x-small), 3.5/4.0(small), 4.5/5.0(large)	BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8	Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0	Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB	Compatible System	Implant Body Diameter(mm)	Implant Platform	BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8	Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0	Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB	Compatible System	Implant Body Diameter(mm)	Implant Platform	Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB	<p>It is compatible with the following systems:</p> <table border="1" data-bbox="743 479 1142 631"> <thead> <tr> <th>Compatible System</th> <th>Implant Body Diameter(mm)</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Osstem TS (K121995)</td> <td>3.5, 3.75</td> <td>Mini</td> </tr> <tr> <td>3.75, 3.77, 4.2, 4.25, 4.4, 4.6, 4.63, 4.65, 4.9, 5.05, 5.08, 5.1</td> <td>Regular</td> </tr> <tr> <td rowspan="2">Straumann Bone Level (only the Roxolid® implants from K140878)</td> <td>3.3</td> <td>NC</td> </tr> <tr> <td>4.1, 4.8</td> <td>RC</td> </tr> </tbody> </table> <p>All digitally designed abutments for use with SIMDA Abutments are intended to be sent to a SIMDA validated milling center for manufacture.</p>	Compatible System	Implant Body Diameter(mm)	Implant Platform	Osstem TS (K121995)	3.5, 3.75	Mini	3.75, 3.77, 4.2, 4.25, 4.4, 4.6, 4.63, 4.65, 4.9, 5.05, 5.08, 5.1	Regular	Straumann Bone Level (only the Roxolid® implants from K140878)	3.3	NC	4.1, 4.8	RC	<p>the Indications for Use Statements and the technological characteristics of The subject device, the primary predicate device. The Indications for Use Statement (IFUS) for the subject device is substantially equivalent in intended use to the primary predicate device. All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. Slight differences in the language of the subject device and primary predicate is Indications for Use statements do not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function. The minor differences between the subject device and the primary predicate device are related to the compatible OEM implant lines and the implant platform diameter.</p>
Compatible System	Implant Body Diameter(mm)	Implant Platform																																																		
Astra OsseoSpeed EV (K120414, K130999)	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4																																																		
Astra Tech Implant System (K101732) Astra Tech Fixture OsseoSpeed Astra Tech Fixture MicroMacro (New indication) (K024111)	3.0S, 3.5S, 4.0S, 4.5, 5.0, 5.0S	3.0(x-small), 3.5/4.0(small), 4.5/5.0(large)																																																		
BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8																																																		
Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0																																																		
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB																																																		
Compatible System	Implant Body Diameter(mm)	Implant Platform																																																		
BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8																																																		
Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0																																																		
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB																																																		
Compatible System	Implant Body Diameter(mm)	Implant Platform																																																		
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB																																																		
Compatible System	Implant Body Diameter(mm)	Implant Platform																																																		
Osstem TS (K121995)	3.5, 3.75	Mini																																																		
	3.75, 3.77, 4.2, 4.25, 4.4, 4.6, 4.63, 4.65, 4.9, 5.05, 5.08, 5.1	Regular																																																		
Straumann Bone Level (only the Roxolid® implants from K140878)	3.3	NC																																																		
	4.1, 4.8	RC																																																		

SIMDA

K252320

Feature	Proposed Device SIMDA Abutment	Primary predicate SIMDA Abutment	SE discussion
	All digitally designed abutments for use with SIMDA Abutments are intended to be sent to a SIMDA validated milling center for manufacture.		
Design Limits for patient-specific abutment (Min. ~ Max.)	Maximum Angulation : 0~25° * Astra OsseoSpeed EV, Astra Tech OsseoSpeed TX : 0~15° Maximum Cuff Height : 0.5~5mm Minimum Diameter : Ø 4.0~ Ø 8.0mm Minimum Thickness : 0.32 (Astra EV) 0.32 (Astra TX), 0.39 (BioHorizons) 0.4 (Biomet 3i), 0.42 (Straumann BLX) Minimum Post Height : 4~6mm	Maximum Angulation : 0~25° Maximum Cuff Height : 0.5~5mm Minimum Diameter : Ø 4.0~ Ø 8.0mm Minimum Thickness : 0.4mm Minimum Post Height : 4~6mm	The minor difference between the two products in the design parameters are as follow. The minimum thickness of the primary predicate device is 0.4, while the subject device can be designed up to 0.32~0.71.
Surface Treatment	None	None	-
Sterile	Non-sterile	Non-sterile	-

K252320

- Ti Base

Feature	Proposed Device SIMDA Abutment	Primary predicate SIMDA Abutment	SE discussion																														
Applicant	SIMDA Co., Ltd.	SIMDA Co., Ltd.	=																														
Part Name	Ti-Base	Ti-Base	=																														
510(K) No.	-	K223663	=																														
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)	Identical																														
Product Code	NHA	NHA	Identical																														
Material	Ti-6Al-4V ELI (ASTM F136) Zirconia Oxide	Ti-6Al-4V ELI (ASTM F136) Zirconia Oxide	Identical																														
Indications For Use	<p>SIMDA Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.</p> <p>It is compatible with the following systems:</p> <p>Pre-Milled Blank, Patient-specific abutment</p> <table border="1"> <thead> <tr> <th>Compatible System</th> <th>Implant Body Diameter(mm)</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td>Astra</td> <td></td> <td></td> </tr> <tr> <td>OsseoSpeed EV (K120414, K130999)</td> <td>3.0, 3.6, 4.2, 4.8, 5.4</td> <td>3.0, 3.6, 4.2, 4.8, 5.4</td> </tr> <tr> <td>Astra Tech Implant System (K101732) Astra Tech Fixture OsseoSpeed Astra Tech Fixture MicroMacro (New indication) (K024111)</td> <td>3.0S, 3.5S, 4.0S, 4.5, 5.0, 5.0S</td> <td>3.0(x-small), 3.5/4.0(small), 4.5/5.0(large)</td> </tr> <tr> <td>BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> </tr> <tr> <td>Biomet 3i Certain® (K130949)</td> <td>3.25, 4.0, 5.0, 6.0</td> <td>3.25, 4.0, 5.0, 6.0</td> </tr> <tr> <td>Straumann BLX Implant (K173961, K181703, K191256)</td> <td>3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5</td> <td>RB, WB</td> </tr> </tbody> </table>	Compatible System	Implant Body Diameter(mm)	Implant Platform	Astra			OsseoSpeed EV (K120414, K130999)	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4	Astra Tech Implant System (K101732) Astra Tech Fixture OsseoSpeed Astra Tech Fixture MicroMacro (New indication) (K024111)	3.0S, 3.5S, 4.0S, 4.5, 5.0, 5.0S	3.0(x-small), 3.5/4.0(small), 4.5/5.0(large)	BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8	Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0	Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB	<p>SIMDA Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.</p> <p>It is compatible with the following systems:</p> <table border="1"> <thead> <tr> <th>Compatible System</th> <th>Implant Body Diameter(mm)</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td>Osstem TS (K121995)</td> <td>3.5, 3.75 3.75, 3.77, 4.2, 4.25, 4.4, 4.6, 4.63, 4.65, 4.9, 5.05, 5.08, 5.1</td> <td>Mini Regular</td> </tr> <tr> <td>Straumann Bone Level (only the Roxolid® implants from K140878)</td> <td>3.3 4.1, 4.8</td> <td>NC RC</td> </tr> </tbody> </table> <p>All digitally designed abutments for use with SIMDA Abutments are intended to be sent to a SIMDA validated milling center for manufacture.</p>	Compatible System	Implant Body Diameter(mm)	Implant Platform	Osstem TS (K121995)	3.5, 3.75 3.75, 3.77, 4.2, 4.25, 4.4, 4.6, 4.63, 4.65, 4.9, 5.05, 5.08, 5.1	Mini Regular	Straumann Bone Level (only the Roxolid® implants from K140878)	3.3 4.1, 4.8	NC RC	<p>The subject device is substantially equivalent in indications and design principles to the primary predicate device listed above. Provided tables are comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device. The Indications for Use Statement (IFUS) for the subject device is substantially equivalent in intended use to the primary predicate device. All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. Slight differences in the language of the subject device and primary predicate is Indications for Use statements do not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function. The minor differences between the subject device and the primary predicate device are related to the compatible OEM implant lines and the implant platform diameter.</p>
Compatible System	Implant Body Diameter(mm)	Implant Platform																															
Astra																																	
OsseoSpeed EV (K120414, K130999)	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4																															
Astra Tech Implant System (K101732) Astra Tech Fixture OsseoSpeed Astra Tech Fixture MicroMacro (New indication) (K024111)	3.0S, 3.5S, 4.0S, 4.5, 5.0, 5.0S	3.0(x-small), 3.5/4.0(small), 4.5/5.0(large)																															
BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8																															
Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0																															
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB																															
Compatible System	Implant Body Diameter(mm)	Implant Platform																															
Osstem TS (K121995)	3.5, 3.75 3.75, 3.77, 4.2, 4.25, 4.4, 4.6, 4.63, 4.65, 4.9, 5.05, 5.08, 5.1	Mini Regular																															
Straumann Bone Level (only the Roxolid® implants from K140878)	3.3 4.1, 4.8	NC RC																															

K252320

Feature	Proposed Device SIMDA Abutment	Primary predicate SIMDA Abutment	SE discussion																		
	<p>Ti-Base</p> <table border="1"> <thead> <tr> <th>Compatible System</th> <th>Implant Body Diameter(mm)</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td>BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> </tr> <tr> <td>Biomet 3i Certain® (K130949)</td> <td>3.25, 4.0, 5.0, 6.0</td> <td>3.25, 4.0, 5.0, 6.0</td> </tr> <tr> <td>Straumann BLX Implant (K173961, K181703, K191256)</td> <td>3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5</td> <td>RB, WB</td> </tr> </tbody> </table> <p>Multi-unit abutment</p> <table border="1"> <thead> <tr> <th>Compatible System</th> <th>Implant Body Diameter(mm)</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td>Straumann BLX Implant (K173961, K181703, K191256)</td> <td>3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5</td> <td>RB, WB</td> </tr> </tbody> </table> <p>Multi-unit Abutment is only compatible with Straumann BLX Implant System.</p> <p>All digitally designed abutments for use with SIMDA Abutments are intended to be sent to a SIMDA validated milling center for manufacture.</p>	Compatible System	Implant Body Diameter(mm)	Implant Platform	BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8	Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0	Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB	Compatible System	Implant Body Diameter(mm)	Implant Platform	Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB		
Compatible System	Implant Body Diameter(mm)	Implant Platform																			
BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8																			
Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0																			
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB																			
Compatible System	Implant Body Diameter(mm)	Implant Platform																			
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB																			
Titanium base	Angulation	0	0	Identical																	
	Gingival collar	3.8, 3.9, 4.0, 4.2, 4.3, 4.5, 5.2, 5.5, 5.8, 6.2	3.8, 4.0, 4.5	The minor difference between the two products in the gingival collar are as follow. The gingival collar of predicate device is 3.8, 3.9, 4.0, 4.2, 4.3, 4.5, 5.0, 5.2, 5.4, 5.8, 6.0, while the subject device is 3.8, 4.0, 4.5.																	
	Post height	3.5, 5.5	3.5, 5.5	Identical																	
	Thickness	0.18~1.11	0.16~0.87	Identical																	
Design Limits for Zirconia top-half (Min. ~ Max.)	<ul style="list-style-type: none"> - Post Angle (°): 0~15 - Cuff Height (mm): 0.5~5.0 -Post Length (mm): 4.0~6.0 -Diameter (Ø, mm): 5.0~8.0 -Thickness (mm): 0.33 	<ul style="list-style-type: none"> - Post Angle (°): 0~15 - Cuff Height (mm): 0.5~5.0 -Post Length (mm): 4.0~6.0 -Diameter (Ø, mm): 5.0~8.0 -Thickness (mm): 0.4 	Identical																		
Prosthesis Attachment	Cement-retained, Screw-retained	Cement-retained, Screw-retained	Identical																		
Surface Treatment	None	None	-																		
Sterile	Non-sterile	Non-sterile	Identical																		

K252320

- Multi-unit Abutment

Feature	Proposed Device SIMDA Abutment	Primary predicate URIS OMNI Narrow System & Prosthetic																		
Applicant	SIMDA Co., Ltd.	TruAbutment Inc.																		
Part Name	Multi-unit Abutment	Multi-unit Straight Abutment																		
510(K) No.	-	K200817																		
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)																		
Product Code	NHA	NHA																		
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)																		
Indications For Use	<p>SIMDA Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.</p> <p>It is compatible with the following systems:</p> <p>Pre-Milled Blank, Patient-specific abutment</p> <table border="1"> <thead> <tr> <th>Compatible System</th> <th>Implant Body Diameter(mm)</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td>Astra OsseoSpeed EV (K120414, K130999)</td> <td>3.0, 3.6, 4.2, 4.8, 5.4</td> <td>3.0, 3.6, 4.2, 4.8, 5.4</td> </tr> <tr> <td>Astra Tech Implant System (K101732) Astra Tech Fixture OsseoSpeed Astra Tech Fixture MicroMacro (New indication) (K024111)</td> <td>3.0S, 3.5S, 4.0S, 4.5, 5.0, 5.0S</td> <td>3.0(x-small), 3.5/4.0(small), 4.5/5.0(large)</td> </tr> <tr> <td>BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> </tr> <tr> <td>Biomet 3i Certain® (K130949)</td> <td>3.25, 4.0, 5.0, 6.0</td> <td>3.25, 4.0, 5.0, 6.0</td> </tr> <tr> <td>Straumann BLX Implant (K173961, K181703, K191256)</td> <td>3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5</td> <td>RB, WB</td> </tr> </tbody> </table>	Compatible System	Implant Body Diameter(mm)	Implant Platform	Astra OsseoSpeed EV (K120414, K130999)	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4	Astra Tech Implant System (K101732) Astra Tech Fixture OsseoSpeed Astra Tech Fixture MicroMacro (New indication) (K024111)	3.0S, 3.5S, 4.0S, 4.5, 5.0, 5.0S	3.0(x-small), 3.5/4.0(small), 4.5/5.0(large)	BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8	Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0	Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB	<p>Multi-Unit Straight Abutment is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of multiple-unit cement retained restorations.</p>
Compatible System	Implant Body Diameter(mm)	Implant Platform																		
Astra OsseoSpeed EV (K120414, K130999)	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4																		
Astra Tech Implant System (K101732) Astra Tech Fixture OsseoSpeed Astra Tech Fixture MicroMacro (New indication) (K024111)	3.0S, 3.5S, 4.0S, 4.5, 5.0, 5.0S	3.0(x-small), 3.5/4.0(small), 4.5/5.0(large)																		
BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8																		
Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0																		
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB																		

K252320

Feature	Proposed Device SIMDA Abutment	Primary predicate URIS OMNI Narrow System & Prosthetic																		
	<p>Ti-Base</p> <table border="1" data-bbox="456 510 895 913"> <thead> <tr> <th>Compatible System</th> <th>Implant Body Diameter(mm)</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td>BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> </tr> <tr> <td>Biomet 3i Certain® (K130949)</td> <td>3.25, 4.0, 5.0, 6.0</td> <td>3.25, 4.0, 5.0, 6.0</td> </tr> <tr> <td>Straumann BLX Implant (K173961, K181703, K191256)</td> <td>3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5</td> <td>RB, WB</td> </tr> </tbody> </table> <p>Multi-unit abutment</p> <table border="1" data-bbox="456 972 895 1122"> <thead> <tr> <th>Compatible System</th> <th>Implant Body Diameter(mm)</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td>Straumann BLX Implant (K173961, K181703, K191256)</td> <td>3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5</td> <td>RB, WB</td> </tr> </tbody> </table> <p>Multi-unit Abutment is only compatible with Straumann BLX Implant System.</p> <p>All digitally designed abutments for use with SIMDA Abutments are intended to be sent to a SIMDA validated milling center for manufacture.</p>	Compatible System	Implant Body Diameter(mm)	Implant Platform	BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8	Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0	Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB	Compatible System	Implant Body Diameter(mm)	Implant Platform	Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB	
Compatible System	Implant Body Diameter(mm)	Implant Platform																		
BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8																		
Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0																		
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB																		
Compatible System	Implant Body Diameter(mm)	Implant Platform																		
Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB																		
Diameters	4.6/4.8mm	5.0mm																		
Lengths	G/H : 3.0mm	G/H : 1.0/2.0/3.0/4.0/5.0/6.0mm																		
Surface Treatment	None	None																		
Sterile	Non-sterile	Non-sterile																		
SE	<p>The subject device and predicate devices (K200817) have the same intended use, have similar technological characteristic, and are made of similar materials. The subject device and predicate devices have similar physical dimensions, including diameter. Therefore, the subject device is substantially equivalent to the currently cleared devices. The cuff height of the primary predicate device is 1.0mm~6.0mm, while the subject device is less than 4.0mm and are always combined with Multi-unit Base, increasing the post height to a minimum of 4.5mm.</p>																			

K252320

- Multi-unit Base

Feature	Proposed Device SIMDA Abutment	Primary predicate URIS OMNI Narrow System & Prosthetic																		
Applicant	SIMDA Co., Ltd.	TruAbutment Inc.																		
Part Name	Multi-unit Base	Multi-unit Base																		
510(K) No.	-	K200817																		
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)																		
Product Code	NHA	NHA																		
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)																		
Indications For Use	<p>SIMDA Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.</p> <p>It is compatible with the following systems:</p> <p>Pre-Milled Blank, Patient-specific abutment</p> <table border="1"> <thead> <tr> <th>Compatible System</th> <th>Implant Body Diameter(mm)</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td>Astra OsseoSpeed EV (K120414, K130999)</td> <td>3.0, 3.6, 4.2, 4.8, 5.4</td> <td>3.0, 3.6, 4.2, 4.8, 5.4</td> </tr> <tr> <td>Astra Tech Implant System (K101732) Astra Tech Fixture OsseoSpeed Astra Tech Fixture MicroMacro (New indication) (K024111)</td> <td>3.0S, 3.5S, 4.0S, 4.5, 5.0, 5.0S</td> <td>3.0(x-small), 3.5/4.0(small), 4.5/5.0(large)</td> </tr> <tr> <td>BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> </tr> <tr> <td>Biomet 3i Certain® (K130949)</td> <td>3.25, 4.0, 5.0, 6.0</td> <td>3.25, 4.0, 5.0, 6.0</td> </tr> <tr> <td>Straumann BLX Implant (K173961, K181703, K191256)</td> <td>3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5</td> <td>RB, WB</td> </tr> </tbody> </table>	Compatible System	Implant Body Diameter(mm)	Implant Platform	Astra OsseoSpeed EV (K120414, K130999)	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4	Astra Tech Implant System (K101732) Astra Tech Fixture OsseoSpeed Astra Tech Fixture MicroMacro (New indication) (K024111)	3.0S, 3.5S, 4.0S, 4.5, 5.0, 5.0S	3.0(x-small), 3.5/4.0(small), 4.5/5.0(large)	BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8	Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0	Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB	<p>Multi-unit Base is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations in partially or fully edentulous individuals. It is used to restore a patient's chewing function.</p>
Compatible System	Implant Body Diameter(mm)	Implant Platform																		
Astra OsseoSpeed EV (K120414, K130999)	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4																		
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Feature	Proposed Device SIMDA Abutment	Primary predicate URIS OMNI Narrow System & Prosthetic																		
	<p>Ti-Base</p> <table border="1" data-bbox="456 510 895 913"> <thead> <tr> <th>Compatible System</th> <th>Implant Body Diameter(mm)</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td>BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> <td>3.0, 3.4, 3.8, 4.6, 5.8</td> </tr> <tr> <td>Biomet 3i Certain® (K130949)</td> <td>3.25, 4.0, 5.0, 6.0</td> <td>3.25, 4.0, 5.0, 6.0</td> </tr> <tr> <td>Straumann BLX Implant (K173961, K181703, K191256)</td> <td>3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5</td> <td>RB, WB</td> </tr> </tbody> </table> <p>Multi-unit abutment</p> <table border="1" data-bbox="456 972 895 1122"> <thead> <tr> <th>Compatible System</th> <th>Implant Body Diameter(mm)</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td>Straumann BLX Implant (K173961, K181703, K191256)</td> <td>3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5</td> <td>RB, WB</td> </tr> </tbody> </table> <p>Multi-unit Abutment is only compatible with Straumann BLX Implant System.</p> <p>All digitally designed abutments for use with SIMDA Abutments are intended to be sent to a SIMDA validated milling center for manufacture.</p>	Compatible System	Implant Body Diameter(mm)	Implant Platform	BioHorizons Laser-Lok 3.0 Implant System (K093321) BioHorizons Tapered Internal Implant System (K143022, K071638)	3.0, 3.4, 3.8, 4.6, 5.8	3.0, 3.4, 3.8, 4.6, 5.8	Biomet 3i Certain® (K130949)	3.25, 4.0, 5.0, 6.0	3.25, 4.0, 5.0, 6.0	Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB	Compatible System	Implant Body Diameter(mm)	Implant Platform	Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB	
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Straumann BLX Implant (K173961, K181703, K191256)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB																		
Diameters	4.8/5.0/5.1mm	5.0mm																		
Lengths	4.85/5.0/7.5/12.5mm	4.35/7.35mm																		
Surface Treatment	None	None																		
Sterile	Non-sterile	Non-sterile																		
SE	<p>The subject device and predicate devices (K200817) have the same intended use, have similar technological characteristic, and are made of similar materials. The subject device and predicate devices have similar physical dimensions, including diameter. Therefore, the subject device is substantially equivalent to the currently cleared devices.</p>																			

Summary of Technological Characteristics

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

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic SIMDA abutment in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." *Journal of Testing and Evaluation* 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

Non-clinical Testing

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Fatigue Test according to ISO 14801:2016
- End User Steam Sterilization Test according to ISO 17665-1:2006, 17665-2:2009 and ANSI/AAMI ST79:2010.
- Biocompatibility tests according to ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010.

Non-clinical test data was used to evaluate the proposed device's substantial equivalence compared to the primary predicate. The results of the above tests have met the criteria of the standard and demonstrated the substantial equivalence with the primary predicate.

Non-clinical testing was conducted in accordance with FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments", and it consisted of testing finished assembled implant/abutment systems of the worst-case scenario through fatigue testing.

Dimensional analysis and reverse engineering of the implant-to-abutment connection platform were performed, including an assessment of maximum and minimum dimensions of critical design aspects, tolerances, and cross-sectional images of the submission device and compatible implant body as well as the OEM implant body, the OEM implant abutment, and the OEM abutment screw. The testing aided implant to abutment compatibility and has established substantial equivalency of the proposed device with reference devices.

Clinical testing was not necessary to establish substantial equivalency of the device.

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Conclusion

SIMDA Abutments constitute a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its primary predicate. Therefore, SIMDA Abutment and its predicate are substantially equivalent.