Simda Co., Ltd.
Cha Young Woo
Regulatory Affairs Manager
156-4, Gamjeon-dong
Busan, Sasang-gu
REPUBLIC OF KOREA

October 26, 2023

Re: K232271
Trade/Device Name: SIMDA abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 28, 2023
Received: July 31, 2023

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232271

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:

Compatible System	Implant Body Diameter(mm)	Implant Platform
Dentium SuperLine (K160965)	3.6, 4.0, 4.5, 5.0, 6.0	Regular
Megagen AnyRidge® (K140091)	3.5, 4.0, 4.5, 5.0	Regular
Nobel Active 3.0 (K102436) Nobel Active Internal Connection Implant (K071370) Nobel Active Wide platform (K133731)	3.0	3.0
	3.5	NP
	4.3, 5.0	RP
	5.5	WP
Screw Vent® and Tapered Screw Vent® (K013227)	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SIMDA

K 232271 510(k) Summary

Applicant

Name:	SIMDA Co., Ltd.
Address:	156-4, Gamjeon-dong, Sasang-gu, Busan, South Korea
Phone:	+82 70 4256 2855
Contact:	Young Woo, Cha
Email:	Email: chassi0406@gmail.com
Date Prepared:	10/25/2023

Subject Device

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

Primary Predicate

Trade Name:	SIMDA Abutment (K223663)
Common Name:	Abutment, Implant, Dental, Endosseous
Classification Name	Endosseous dental implant abutment
Product Code:	NHA
Panel:	Dental
Regulation Number:	21 CFR 872.3630
Device Class:	Class II

Reference Device

Trade Name:	Dentium Company Limited Implantium (K160965) by Dentium Co., Ltd.
Common Name:	Abutment, Implant, Dental, Endosseous
Classification Name	Endosseous dental implant abutment
Product Code:	NHA
Panel:	Dental
Regulation Number:	21 CFR 872.3630
Device Class:	Class II

Trade Name:	Xpeed AnyRidge Internal Implant System (K140091) by MegaGen Implant Co., Ltd.
Common Name:	Abutment, Implant, Dental, Endosseous
Classification Name	Endosseous dental implant abutment
Product Code:	NHA
Panel:	Dental
Regulation Number:	21 CFR 872.3630
Device Class:	Class II

Trade Name:	Nobelactive 3.0 (K102436) By Nobel Biocare Nobelactive Internal Connection Implant (K071370) By Nobel Biocare Nobelactive Wide Platform (Wp) (K133731) By Nobel Biocare
Common Name:	Abutment, Implant, Dental, Endosseous
Classification Name	Endosseous dental implant abutment
Product Code:	NHA
Panel:	Dental
Regulation Number:	21 CFR 872.3630
Device Class:	Class II

Trade Name:	Screw Vent® and Tapered Screw Vent® (K013227) by Sulzer Dental Inc.
Common Name:	Abutment, Implant, Dental, Endosseous
Classification Name	Endosseous dental implant abutment
Product Code:	NHA
Panel:	Dental
Regulation Number:	21 CFR 872.3630
Device Class:	Class II

Trade Name:	Nobel Active Wide Platform (K133731) by Sulzer Dental Inc.
Common Name:	Abutment, Implant, Dental, Endosseous
Classification Name	Endosseous dental implant abutment
Product Code:	NHA
Panel:	Dental
Regulation Number:	21 CFR 872.3630
Device Class:	Class II

Trade Name:	INCORIS ZI (K123664)
Common Name:	Powder, porcelain
Classification Name	Porcelain powder of clinical use
Product Code:	EIH
Panel:	Dental
Regulation Number:	21 CFR 872.6660
Device Class:	Class II

Trade Name:	Malta, 3M ESPE AG Dental Products (K100756)
Common Name:	Self adhesive cement
Classification Name	Dental cement other zinc oxide-eugenol
Product Code:	EMA
Panel:	Dental
Regulation Number:	21 CFR 872.3275
Device Class:	Class II

Device Description

SIMDA Abutment is made of titanium alloy (Ti-6Al-4V ELI, ASTM F136) intended for use as an aid in prosthetic restoration. It consists of Pre-Milled Blank and Ti-Base abutment. It has a pre-manufactured connection interface that fits directly to an endosseous dental implant.

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	∅4.0~∅8.0
Minimum and Maximum length of abutment	4.5~13mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4~8mm
Minimum wall thickness at abutment/implant interface	0.4mm
Minimum and Maximum abutment angle	0~25º

Ti Base consists of a two-piece abutment, where the titanium base is a pre-manufactured abutment 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.

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

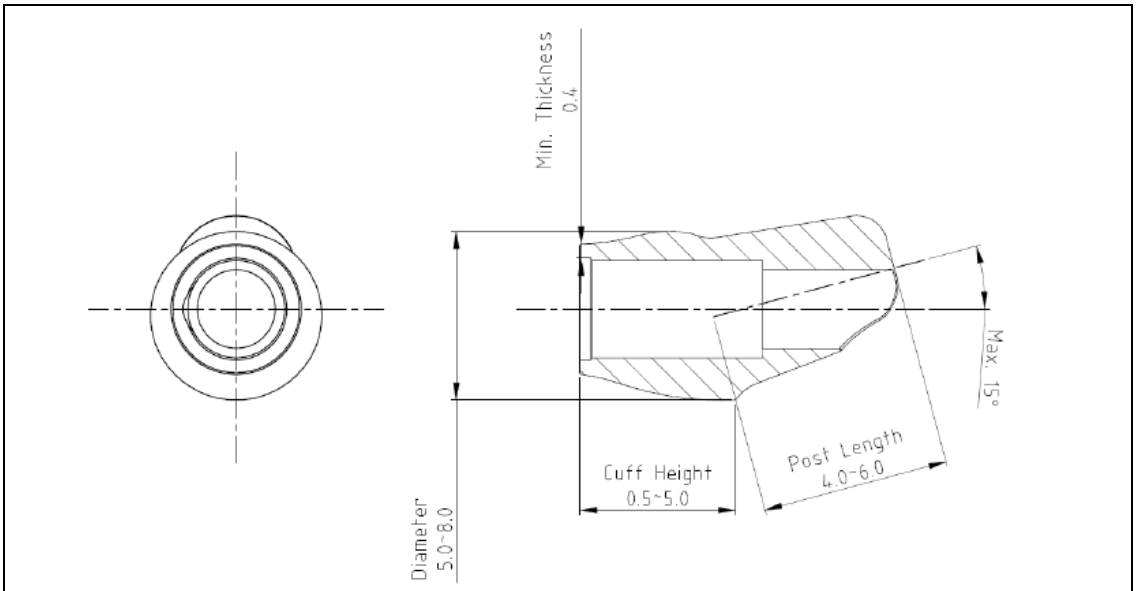
Raw material blanks

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

Cement

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

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	0.4

SIMDA Abutment is a device that can only be sold, distributed, or used upon the order of an authorized healthcare provider, generally referred to as prescription (Rx) devices.

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:

Compatible System	Implant Body Diameter(mm)	Implant Platform
Dentium SuperLine (K160965)	3.6, 4.0, 4.5, 5.0, 6.0	Regular
Megagen AnyRidge® (K140091)	3.5, 4.0, 4.5, 5.0	Regular
Nobel Active 3.0 (K102436) Nobel Active Internal Connection Implant (K071370) Nobel Active Wide platform (K133731)	3.0	3.0
	3.5	NP
	4.3, 5.0	RP
	5.5	WP
Screw Vent® and Tapered Screw Vent® (K013227)	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

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

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.

Non-clinical Testing

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 data submitted, referenced, or relied upon to demonstrate substantial equivalen ce included:

- Fatigue testing followed ISO 14801 and the FDA special controls guidance document.
- 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 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 scenarios through fatigue testing.

Dimensional analysis and reverse engineering of critical features of critical features and tolerances of the implant-to-abutment connection platform were performed on the OEM implant body, the OEM abutment, and the OEM abutment screw. Cross sectional images were provided to demonstrate substantially equivalent compatibility. The testing aided implant to abutment compatibility and has established substantial equivalency of the proposed device with the predicate device.
Clinical testing was not necessary to establish substantial equivalency of the device.

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
  - Dentium SuperLine (K160965)
  - Megagen AnyRidge® (K140091)
  - Nobel Active 3.0 (K102436)
  - Nobel Active Internal Connection Implant (K071370)
  - Nobel Active Wide Platform (WP) (K133731)
  - Screw Vent® and Tapered Screw Vent® (K013227)

Comparison between Primary predicates

Pre-Milled Blank

<table>
<tr><th>Feature</th><th>Proposed Device
SIMDA Abutment</th><th>Primary predicate
SIMDA Abutment</th><th>SE discussion</th></tr>
<tr><td>Applicant</td><td>SIMDA Co., Ltd.</td><td>SIMDA Co., Ltd.</td><td>-</td></tr>
<tr><td>Part Name</td><td>Pre-Milled Blank</td><td>Pre-Milled Blank</td><td>-</td></tr>
<tr><td>510(K) No.</td><td>-</td><td>K223663</td><td>-</td></tr>
<tr><td>Classification Name</td><td>Endosseous Dental Implant Abutments (872.3630)</td><td>Endosseous Dental Implant Abutments (872.3630)</td><td>Identical</td></tr>
<tr><td>Product Code</td><td>NHA</td><td>NHA</td><td>Identical</td></tr>
<tr><td>Screw and Abutment Material</td><td>Ti-6Al-4V ELI
(ASTM F136)</td><td>Ti-6Al-4V ELI
(ASTM F136)</td><td>Identical</td></tr>
<tr><td>Indications For Use</td><td>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:</td><td>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:
<table>
<tr><th>Compatible System</th><th>Implant Body Diameter(mm)</th><th>Implant Platform</th></tr>
<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>
</table></td><td>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</td></tr>
</table>

<table>
<tr><th>Feature</th><th>Proposed Device
SIMDA Abutment</th><th>Primary predicate
SIMDA Abutment</th><th>SE discussion</th></tr>
<tr><td></td><td>
<table>
<tr><th>Compatible System</th><th>Implant Body Diameter(mm)</th><th>Implant Platform</th></tr>
<tr><td>Dentium SuperLine (K160965)</td><td>3.6, 4.0, 4.5, 5.0, 6.0</td><td>Regular</td></tr>
<tr><td>Megagen AnyRidge® (K140091)</td><td>3.5, 4.0, 4.5, 5.0</td><td>Regular</td></tr>
<tr><td rowspan="4">Nobel Active 3.0 (K102436)
Nobel Active Internal Connection Implant (K071370)
Nobel Active Wide platform (K133731)</td><td>3.0</td><td>3.0</td></tr>
<tr><td>3.5</td><td>NP</td></tr>
<tr><td>4.3, 5.0</td><td>RP</td></tr>
<tr><td>5.5</td><td>WP</td></tr>
<tr><td rowspan="3">Screw Vent® and Tapered Screw Vent® (K013227)</td><td>3.7, 4.1</td><td>3.5</td></tr>
<tr><td>4.7</td><td>4.5</td></tr>
<tr><td>6.0</td><td>5.7</td></tr>
</table>
All digitally designed abutments for use with SIMDA Abutments are intended to be sent to a SMIDA validated milling center for manufacture.
</td><td>All digitally designed abutments for use with SIMDA Abutments are intended to be sent to a SMIDA validated milling center for manufacture.</td><td>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 and the new compatibilities have been verified via reverse engineering and performance testing.</td></tr>
<tr><td>Dimension of Pre-milled Blank</td><td>Total length (mm) : 28.05, 28.25, 28.37, 28.4, 28.45, 28.6, 28.65, 28.9, 28.92
Diameter (mm) : 10, 14</td><td>Total length (mm) : 27.88, 28.92, 30.8, 28.9, 28.92
Diameter (mm) : 10, 14</td><td>The minor difference between the two products in the total length are as follow.
The total length of predicate device is 27.88, 28.92, 30.8, 28.9, 28.92, while the subject device is 28.05, 28.25, 28.37, 28.4, 28.45, 28.6, 28.65, 28.9, 28.92 .</td></tr>
<tr><td>Design Limits for patient-specific abutment (Min. ~ Max.)</td><td>Maximum Angulation : 0~25°
Maximum Cuff Height : 0.5~5mm
Minimum Diameter : Ø 4.0~ Ø 8.0mm
Minimum Thickness : 0.39~0.55mm
Minimum Post Height : 4~6mm</td><td>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</td><td>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 0.39~0.55. This change in technological characteristics was evaluated as part of the performance testing and was determined to not impact the performance of the device."</td></tr>
<tr><td>Surface Treatment</td><td>None</td><td>None</td><td>-</td></tr>
<tr><td>Sterile</td><td>Non-sterile</td><td>Non-sterile</td><td>-</td></tr>
</table>

Ti Base

<table>
<tr><th>Feature</th><th>Proposed Device
SIMDA Abutment</th><th>Primary predicate
SIMDA Abutment</th><th>SE discussion</th></tr>
<tr><td>Applicant</td><td>SIMDA Co., Ltd.</td><td>SIMDA Co., Ltd.</td><td>-</td></tr>
<tr><td>Part Name</td><td>Ti-Base</td><td>Ti-Base</td><td>-</td></tr>
<tr><td>510(K) No.</td><td>-</td><td>K223663</td><td>-</td></tr>
<tr><td>Classification Name</td><td>Endosseous Dental Implant Abutments (872.3630)</td><td>Endosseous Dental Implant Abutments (872.3630)</td><td>Identical</td></tr>
<tr><td>Product Code</td><td>NHA</td><td>NHA</td><td>Identical</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V ELI
(ASTM F136)
Zirconia Oxide</td><td>Ti-6Al-4V ELI
(ASTM F136)
Zirconia Oxide</td><td>Identical</td></tr>
<tr><td>Indications For Use</td><td>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:
<table>
<tr><th>Compatible System</th><th>Implant Body Diameter(mm)</th><th>Implant Platform</th></tr>
<tr><td>Dentium SuperLine (K160965)</td><td>3.6, 4.0, 4.5, 5.0, 6.0</td><td>Regular</td></tr>
<tr><td>Megagen AnyRidge® (K140091)</td><td>3.5, 4.0, 4.5, 5.0</td><td>Regular</td></tr>
<tr><td rowspan="4">Nobel Active 3.0 (K102436)
Nobel Active Internal Connection Implant (K071370)
Nobel Active Wide platform (K133731)</td><td>3.0</td><td>3.0</td></tr>
<tr><td>3.5</td><td>NP</td></tr>
<tr><td>4.3, 5.0</td><td>RP</td></tr>
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<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>
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</table>

Feature	Proposed Device SIMDA Abutment		Primary predicate SIMDA Abutment	SE discussion
				diameter and the new compatibilities have been verified via reverse engineering and performance testing.
Titanium base	Angulation	0	0	Idential
	Gingival collar	3.5, 3.8, 4.0, 4.3, 4.5, 5.0, 6.5	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, 4.0, 4.5, while the subject device is 3.5, 3.8, 4.0, 4.3, 4.5, 5.0, 6.5.
	Post height	3.5, 5.5	3.5, 5.5	Idential
	Thickness	0.16~0.87	0.16~0.87	Idential
Design Limits for Zirconia top-half (Min. ~ Max.)	- 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		- 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	Idential
Prothesis Attachment	Cement-retained, Screw-retained		Cement-retained, Screw-retained	Identical
Surface Treatment	None		None	-
Sterile	Non-sterile		Non-sterile	Identical

Substantial Equivalence Discussion

SIMDA Abutment incorporates the same material, indications for use, dimension, design, abutment seat, screw seat, anatomical site, connection, type of retention and technological characteristics as the primary predicate.

The Indications for Use of the subject and primary predicate are identical other than the compatible implant bodies. This difference is mitigated by fatigue testing, reverse engineering, dimensional analysis, and identification of reference predicate for compatible implant bodies. Both the predicate and subject devices are intended to be milled into patient-specific abutments using CAD/CAM technology under the manufacturing control of the sponsor.

Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicate and do not raise different questions of safety and effectiveness than the predicate.

SIMDA Abutments are compatible with reference devices (K121995 and K140878). Each SIMDA Abutment platform has a precision implant/abutment interface corresponding to the implant system predicate for that platform.

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.