September 15, 2021

TruAbutment Inc.
Chris Choi
Director
17666 Fitch
Irvine, California 92614

Re: K203649
Trade/Device Name: TruAbutment DS, TruBase
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 26, 2021
Received: August 16, 2021

Dear Chris Choi:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Andrew 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203649

Device Name
TruAbutment DS, TruBase

Indications for Use *(Describe)*
TruAbutment DS
TruAbutment DS is a patient-specific CAD/CAM abutment, directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. It is compatible with the following systems:

• MIS C1 Conical Connection Implant (K172505, K112162)
: 3.3 (NP) 3.75, 4.2, 5.0 (SP, WP)
• Neodent Implant System - GM Helix (K163194, K180536)
: 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0)
• Nobel Biocare Groovy Implants (K050258)
: 3.5. 4.3, 5.0, 6.0 (NP, RP, WP, 6.0)
• Straumann BLX Implant (K173961, K181703, K191256)
: 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB, WB)
• Straumann Tissue Level Implant (K111357)
: 3.3(NNC)

All digitally designed abutments and/or coping for use with the TruAbutment DS abutments are intended to be sent to a TruAbutment-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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203649

Device Name
TruAbutment DS, TruBase

Indications for Use *(Describe)*
TruBase
TruBase is a titanium component that is directly connected to endosseous dental implants to provide support for patient-specific prosthetic restorations, such as copings or crowns. It is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible with the following systems:

• MIS C1 Conical Connection Implant (K172505, K112162)
: 3.3 (NP) 3.75, 4.2, 5.0 (SP, WP)
• Neodent Implant System - GM Helix (K163194, K180536)
: 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0)
• Nobel Biocare Groovy Implants (K050258)
: 3.5. 4.3, 5.0, 6.0 (NP, RP, WP, 6.0)
• Straumann BLX Implant (K173961, K181703, K191256)
: 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB, WB)
• Straumann Tissue Level Implant (K111357)
: 3.3(NNC)

All digitally designed zirconia superstructure for use with the TruBase are intended to be sent to a TruAbutment-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)

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510(k) Summary
K203649

Submitter
TruAbutment Inc.
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Device Information

- Trade Name: TruAbutment DS, TruBase
- 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
- Date prepared: 09/14/2021

Primary Predicate / Reference Devices:

Primary Predicate:

- TruAbutment DS, TruBase (K202579) by TruAbutment Inc.

Reference Devices:

- MIS C1 Narrow Platform Conical Connection Implant System (K172505) by MIS Implants Technologies Ltd.
- MIS C1 Standard, Wide Platform Conical Connection Implants (K112162) by MIS Implants Technologies Ltd.
- Neodent Implant System - GM Helix (K163194) by Straumann USA, LLC.
- Neodent Implant System - GM Helix (K180536) by PaxMed International, LLC.
- Nobel Biocare Groovy Implants (K050258) by Nobel Biocare AB.
- Straumann BLX Implant System (K173961) by Straumann USA, LLC.
- Straumann BLX Line Extension - Implants (K181703) by Straumann USA, LLC.
- Straumann BLX Ø3.5 Mm Implants (K191256) by Straumann USA, LLC.
- Straumann Narrow Neck CrossFit (NNC) Ø3.3mm Dental Implant System (K111357) by Straumann USA.

General Description

TruAbutment DS

TruAbutment DS system includes patient-specific abutments which are placed into the dental implant to provide support for the prosthetic restoration. The subject abutments are indicated for cemented or screw-retained restorations. The patient-specific abutment and abutment screw are made of Titanium grade Ti-6A1-4V ELI (meets ASTM Standard F-136). Each patient-specific abutment is supplied with two identical screws which are used for:
(1) For fixing into the endosseous implant
(2) For dental laboratory use during construction of related restoration.
The abutment is placed over the implant shoulder and mounted into the implant with the provided screw. The design and manufacturing of the patient-specific abutments take into consideration the shape of the final prosthesis based on the patient's intra-oral indications using CAD/CAM system during the manufacturing. All manufacturing processes of TruAbutment DS are conducted at the TruAbutment milling center and provided to the authorized end-user as a final patient-specific abutment.

Mechanical resistance of the implant-abutment connection is essential to ensure the correct long-term functional performance of the complete dental restoration. Dimensional compatibility and mechanical performance of bases and screws together with the underlying implant are of primary importance. These concepts are the basis upon which the system design characteristics and functional performance are established.

The TruAbutment DS 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.

Design Limitation for TruAbutment DS

Design Parameter	Design Limit
Minimum and Maximum abutment angle(°)	0 ~ 25
Minimum and Maximum cuff height(mm)	0.5 ~ 6.0
Minimum and Maximum diameter at abutment/implant interface(Ø,mm)	3.8 ~ 8.0
Minimum thickness(mm)	0.4
Minimum and Maximum length of abutment post (length above the abutment collar / gingival height) (mm)	4.0 ~ 7.0

TruBase

TruBase 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 superstructure (the second part of the two-piece abutment) that composes the final abutment. The system also includes a TruBase screw for fixation to the implant body.

TruBase abutments are made of titanium alloy conforming to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications and are provided in various prosthetic platform diameters (MIS C1 Narrow Platform

Conical Connection Implant (K172505, K112162): 3.3 (NP), 3.75, 4.2, 5.0 (SP,WP), Neodent Implant System - GM Helix (K163194, K180536): 3.5, 3.75, 4.0, 4.3, 5.0 (3.0 6.0 (3.0), Nobel Biocare Groovy Implants (K050258): 3.5. 4.3, 5.0, 6.0 (NP, RP, WP, 6.0), Straumann BLX Implant System (K173961, K181703, K191256): 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB, WB), Straumann Tissue Level (K111357): 3.3 (NNC). The TruBase screws are composed of titanium alloy per ASTM F136.

CAD/CAM customized superstructure that composes the final abutment is intended to be sent to a TruAbutment-validated milling center to be designed and milled, according to the prosthetic planning and patient clinical situation. The superstructure is cemented to the TruBase in the lab. Use "RelyX Unicem 2Automix" as an adhesive extra orally to connect.

TruBase is provided non-sterile therefore must be sterilized after the cementation of the customized superstructure on the TruBase.

The TruBase 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.

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	Design Limit
Minimum and Maximum angulation(°)	0 ~ 15
Minimum and Maximum cuff height(mm)	0.5 ~ 5.0
Minimum and Maximum diameter at abutment/implant interface(Ø,mm)	5.0 ~ 8.0
Minimum thickness(mm)	0.4
Minimum and Maximum length of abutment post (length above the abutment collar / gingival height) (mm)	4.0 ~ 6.0

Indication for Use

TruAbutment DS

TruAbutment DS is a patient-specific CAD/CAM abutment, directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. It is compatible with the following systems:

- MIS C1 Conical Connection Implant (K172505, K112162)
  : 3.3 (NP) 3.75, 4.2, 5.0 (SP, WP)
- Neodent Implant System - GM Helix (K163194, K180536)
  : 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0)
- Nobel Biocare Groovy Implants (K050258)
  : 3.5. 4.3, 5.0, 6.0 (NP, RP, WP, 6.0)
- Straumann BLX Implant (K173961, K181703, K191256)
  : 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB, WB)
- Straumann Tissue Level Implant (K111357)
  : 3.3(NNC)

All digitally designed abutments and/or coping for use with the TruAbutment DS abutments are intended to be sent to a TruAbutment-validated milling center for manufacture.

TruBase

TruBase is a titanium component that is directly connected to endosseous dental implants to provide support for patient-specific prosthetic restorations, such as copings or crowns. It is indicated for a screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible with the following systems:

- MIS C1 Conical Connection Implant (K172505, K112162)
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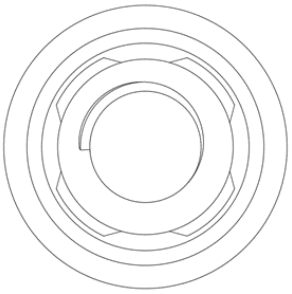
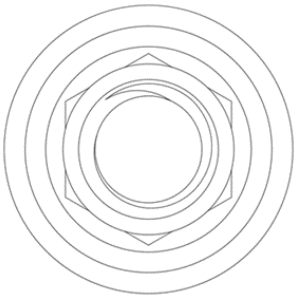
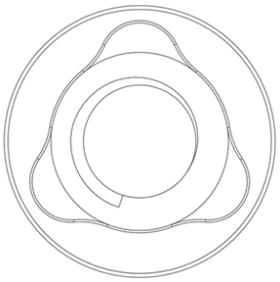
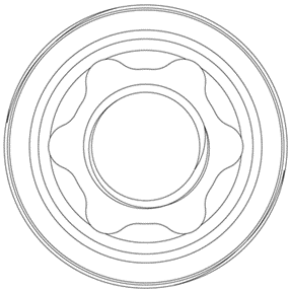
  : 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0)
- Nobel Biocare Groovy Implants (K050258)
  : 3.5. 4.3, 5.0, 6.0 (NP, RP, WP, 6.0)
- Straumann BLX Implant (K173961, K181703, K191256)
  : 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB, WB)
- Straumann Tissue Level Implant (K111357)
  : 3.3(NNC)

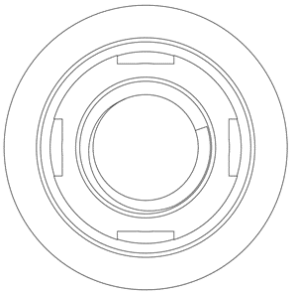
All digitally designed zirconia superstructure for use with the TruBase are intended to be sent to a TruAbutment-validated milling center for manufacture.

TruAbutment DS and TruBase are compatible with the following OEM devices:

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
MIS C1 (K172505, K112162)	3.3	10	C1-10330	Narrow Platform (NP)	 Conical connection
		11.5	C1-11330		
		13	C1-13330		
		16	C1-16330		
	3.75	8	C1-08375	Standard Platform (SP)	
		10	C1-10375		
		11.5	C1-11375		
		13	C1-13375		
		16	C1-16375		
	4.2	8	C1-08420		
		10	C1-10420		
		11.5	C1-11420		
		13	C1-13420		
		16	C1-16420		
	5.0	8	C1-08500	Wide Platform (WP)	
		10	C1-10500		
		11.5	C1-11500		
		13	C1-13500		
		16	C1-16500		
Neodent GM (K163194, K180536)	3.5	8	109.943	3.0	 Grand Morse connection
		10	109.944		
		11.5	109.945		
		13	109.946		
		16	109.947		
		18	109.988		
	3.75	8	109.976		
		10	109.977		
		11.5	109.978		
		13	109.979		
		16	109.980		
		18	109.981		
	4.0	8	109.982		
		10	109.983		
		11.5	109.984		
		13	109.985		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
		16	109.986		
		18	109.987		
	4.3	8	109.948		
		10	109.949		
		11.5	109.950		
		13	109.951		
		16	109.952		
		18	109.989		
	5.0	8	109.953		
		10	109.954		
		11.5	109.955		
		13	109.956		
		16	109.957		
		18	109.990		
	6.0	8	109.1009		
		10	109.1010		
		11.5	109.1011		
		13	109.1012		
Nobel Biocare Groovy Implants (K050258)	3.5	8	32211	Narrow Platform (NP)	 Internal tri-channel connection
		10	32212		
		11.5	36100		
		13	32213		
		16	32214		
	4.3	8	32215	Regular Platform (RP)	
		10	32216		
		11.5	36101		
		13	32217		
		16	32218		
	5.0	8	32219	Wide Platform (WP)	
		10	32220		
		11.5	36102		
		13	32221		
		16	32222		
	6.0	8	32223	6.0	
		10	32224		
		11.5	36103		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
		13	32225		
		16	32226		
Straumann BLX (K173961, K181703, K191256)	3.5	8	061.3308	Regular Base (RB)	 TorcFit connection
		10	061.3310		
		12	061.3312		
		14	061.3314		
		16	061.3316		
		18	061.3318		
	3.75	6	061.4306		
		8	061.4308		
		10	061.4310		
		12	061.4312		
		14	061.4314		
		16	061.4316		
		18	061.4318		
	4.0	6	061.5306		
		8	061.5308		
		10	061.5310		
		12	061.5312		
		14	061.5314		
		16	061.5316		
		18	061.5318		
	4.5	6	061.6306		
		8	061.6308		
		10	061.6310		
		12	061.6312		
		14	061.6314		
		16	061.6316		
		18	061.6318		
	5.0	6	061.7306	Wide Base (WB)	
		8	061.7308		
		10	061.7310		
		12	061.7312		
		14	061.7314		
		16	061.7316		
		18	061.7318		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
	5.5	6	061.8306		
		8	061.8308		
		10	061.8310		
		12	061.8312		
	6.5	6	061.9306		
		8	061.9308		
		10	061.9310		
		12	061.9312		
Straumann Tissue Level (K111357)	3.3	8	033.416S	Narrow Neck Crossfit (NNC)	 CrossFit connection
		10	033.417S		
		12	033.418S		
		14	033.419S		

Summary of Technological Characteristics

The subject device is substantially equivalent to the currently cleared devices. They are substantially equivalent in intended use, material and connection interfaces to the implants are identical for each diameter and connection type. Comparison demonstrating Substantial Equivalence follows at the end of this section.

TruAbutment DS

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruAbutment DS	TruAbutment DS (K202579)
Indications for Use	TruAbutment DS is a patient-specific CAD/CAM abutment, directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. It is compatible with the following systems: MIS C1 Conical Connection Implant (K172505, K112162) : 3.3 (NP) 3.75, 4.2, 5.0 (SP, WP) Neodent Implant System - GM Helix (K163194, K180536) : 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0(3.0) Nobel Biocare Groovy Implants (K050258) : 3.5. 4.3, 5.0, 6.0 (NP, RP, WP, 6.0) Straumann BLX Implant (K173961, K181703, K191256) : 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB, WB) Straumann Tissue Level Implant (K111357,) : 3.3(NNC) All digitally designed abutments and/or coping for use with the TruAbutment DS abutments are intended to be sent to a TruAbutment-validated milling center for manufacture.	TruAbutment DS is a patient-specific CAD/CAM abutment, directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. It is compatible with the following systems: 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 (X-Small, Small, Large) Dentium Company Limited Implantium (K041368): 3.4, 3.8, 4.3, 4.8 (Regular) PrimaConnex™ Internal Connection Implant System(K051614): 3.5, 4.1, 5.0 (SD, RD, WD) Straumann Ø2.9 mm Bone Level Tapered Implants, SC CARES Abutments (K162890): 2.9 (SC) Straumann® Bone Level Tapered Implants (K140878): 3.3, 4.1, 4.8 (NC, RC)

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruAbutment DS	TruAbutment DS (K202579)
		All digitally designed abutments and/or coping for use with the TruAbutment DS abutments are intended to be sent to a TruAbutment-validated milling center for manufacture.
CAD Design Limits	Minimum and Maximum abutment angle(°): 0~25 Minimum and Maximum gingival (cuff) height(mm): 0.5~6.0 Minimum and Maximum diameter at abutment/implant interface(∅,mm): 3.3~8.0 Minimum and Maximum length of abutment(mm): 6.0~11.0 Minimum wall thickness at the abutment/implant interface(mm): 0.4~0.9 Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)(mm): 4.0~7.0	Minimum and Maximum abutment angle: 0~25º Minimum and Maximum Gingival (Cuff) Height: 0.5~6.0mm Minimum and Maximum diameter at abutment/implant interface: ∅3.8~∅8.0 Minimum and Maximum length of abutment: 6~11mm Minimum wall thickness at the abutment/implant interface: 0.4mm Minimum and Maximum length of abutment post (length above the abutment collar/gingival height): 4~7mm
Connection	Internal Connections	Internal Connections
Sterility	Packaged Non-sterile	Packaged Non-sterile
Material	Ti-6AI-4V ELI	Ti-6AI-4V ELI
Abutment Seat	Sits on Taper	Sits on Taper
Anatomical Site	Oral Cavity	Oral Cavity
Construction	Machined	Machined
Type of Retention	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.

TruBase

Attributes	Proposed Device	Primary Predicate Device
Trade Name	**TruBase**	TruBase (K202579)
Indications for Use	TruBase is a titanium component that is directly connected to endosseous dental implants to provide support for patient-specific prosthetic restorations, such as copings or crowns. It is indicated for a screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible with the following systems: MIS C1 Conical Connection Implant (K172505, K112162) : 3.3 (NP) 3.75, 4.2, 5.0 (SP, WP) Neodent Implant System - GM Helix (K163194, K180536) : 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0(3.0) Nobel Biocare Groovy Implants (K050258) : 3.5. 4.3, 5.0, 6.0 (NP, RP, WP, 6.0) Straumann BLX Implant (K173961, K181703, K191256) : 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB, WB) Straumann Tissue Level Implant (K111357) : 3.3(NNC) All digitally designed zirconia superstructure for use with the TruBase are intended to be sent to a TruAbutment-validated milling center for manufacture.	TruBase is a titanium component that is directly connected to endosseous dental implants to provide support for patient-specific prosthetic restorations, such as copings or crowns. It is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible with the following systems: 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 (X-Small, Small, Large) Dentium Company Limited Implantium (K041368): 3.4, 3.8, 4.3, 4.8 (Regular) PrimaConnex™ Internal Connection Implant System(K051614): 3.5, 4.1, 5.0 (SD, RD, WD) Straumann Ø2.9 mm Bone Level Tapered Implants, SC CARES Abutments (K162890): 2.9 (SC) Straumann® Bone Level Tapered Implants (K140878): 3.3, 4.1, 4.8 (NC, RC) Xpeed AnyRidge Internal Implant System

		(K140091): 4.0, 4.4, 4.9, 5.4, 5.9 (3.5) All digitally designed zirconia superstructure for use with the TruBase are intended to be sent to a TruAbutment-validated milling center for manufacture.
CAD Design Limits	Maximum angulation(°): 0~15 Maximum cuff height(mm) 0.5~5.0 Minimum and Maximum diameter at the abutment/implant(Ø,mm): 5.0~ 8.0 Minimum thickness(mm): 0.4 Minimum post height(mm): 4~6	Maximum Angulation 0~15° Maximum Cuff Height 0.5~5mm Minimum Diameter Ø5.0~ Ø8.0mm Minimum Thickness 0.4mm Minimum Post Height 4~6mm
Abutment and Screw Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Implant-to-Abutment Connection(s)	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.
Type of Retention	Screw-retained.	Screw-retained
Material of Superstructure	InCoris Zi (K123664)	InCoris ZI (K123664)
Patient-Specific Design	CAD/CAM manufactured superstructures	CAD/CAM manufactured superstructures
End-User Sterilization	Moist steam sterilization	Moist steam sterilization

Substantial Equivalence Discussion

The subject device (TruAbutment DS) is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. The 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 (TruAbutment DS) is substantially equivalent in intended use to the primary predicate device (K202579). 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 (TruAbutment DS) and primary predicate (K202579) 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 (TruAbutment DS) and the primary predicate device (K202579) are related to the compatible OEM implant lines and the implant platform diameter.

The following subject device (TruBase) is substantially equivalent in indications and design principles to the primary predicate device(K202579) listed above. The subject device (TruBase) and the primary predicate device(K202579) have internal implant interface connections and are made of Ti-6Al-4V ELI (abutments and abutment screws).

The subject devices (TruAbutment DS, TruBase) are to be sterilized by the end-user, the same as primary predicate devices (K202579).
Sterilization validation for the subject devices (TruAbutment DS, TruBase) was performed according to ISO 17665-1 and ISO 17665-2. This sterilization validation method is the same as the primary predicate devices (K202579).

Mechanical performance testing was performed according to ISO 14801. For compatible OEM implant line, worst-case constructs were subjected to static compression and compression fatigue testing. The fatigue limit data for all other implant lines demonstrated the construct strengths to be sufficient for their intended use.

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

Below tests were performed for the reference device (K152559, K200817) and leveraged for the subject device:

- 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 predicate device. The results of the above tests have met the criteria of the standard and demonstrated the substantial equivalence with the predicate device.

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 OEM implant body, OEM abutment, and OEM fixation screw. The testing demonstrated implant to abutment compatibility and has established substantial equivalency of the proposed device with predicate devices.

Comparative fatigue testing of the subject and predicate devices was conducted in accordance with ISO 14801 and FDA Guidance "Class II Special Controls Guidance Document: Rootform Endosseous Dental Implants and Endosseous Dental Implant Abutments", and it consisted of testing finished assembled implant/abutment systems.

Conclusion

The TruAbutment DS, TruBase constitutes 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 predicate devices. Therefore, TruAbutment DS, TruBase, and its predicate are substantially equivalent.