July 08, 2021

TruAbutment Inc.
Chris Choi
Director
17742 Cowan
Irvine, California 92614

Re: K202579
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: April 26, 2021
Received: June 7, 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 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)*
K202579

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:

- 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)

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.

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)*
K202579

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:

- 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.

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.

510(k) Summary
K202579

Submitter
TruAbutment Inc.
Eunjin Jang
17742 Cowan,
Irvine, CA 92614
USA
Email: Eunjin.jang@truabutment.com
Phone: 1-714-956-1488

Official Correspondent
TruAbutment Inc.
Chris Choi
17742 Cowan,
Irvine, CA 92614
USA
Email: chris.choi@truabutment.com
Phone: 1-714-956-1488

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: 07/07/2021

Primary Predicate:

- TruAbutment DS, TruBase S (K201197) by TruAbutment Inc.

Reference Devices:

- Astra Tech OsseoSpeed, Astra Tech Fixture MicroMacro (New Indication) (K024111) by Astra Tech, Inc.
- Astra Tech Implant System (K101732) by Astra Tech AB.
- Dentium Company Limited Implantium (K041368) by Dentium Co., Ltd.
- Lifecore PrimaConnex™ Internal Connection Implant System(K051614) by Lifecore Biomedical, Inc.
- Xpeed AnyRidge Internal Implant System (K140091) by MegaGen Implant Co., Ltd.
- Straumann Ø2.9 mm Bone Level Tapered Implants, SC CARES Abutments (K162890) by Straumann USA, LLC.
- Straumann® Bone Level Tapered Implants (K140878) by Straumann USA, LLC.

General Description

TruAbutment DS

TruAbutment DS system includes patient-specific abutments which are placed into the dental implant to provide support for 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.

The following table shows the subject device abutment platform sizes for each of the OEM implant lines and sizes.

TruAbutment Platform Diameter / Compatible Implant System	TruAbutment DS Engaging	TruAbutment DS Non-Engaging
Astra Tech OsseoSpeed (K101732, K024111)		
X-small	o	o
Small	o	o
Large	o	o
Dentium SuperLine (K041368)		
Regular	o	o
Keystone PrimaConnex (K051614)		
3.5 (SD)	o	o
4.1 (RD)	o	o
5.0 (WD)	o	o
Straumann Bone Level (K162890) (K140878)		
SC	o	o
NC	o	o
RC	o	o

Design Limitation for TruAbutment DS

Design parameter	Design Limit
Minimum and Maximum abutment angle	0~25°
Minimum and Maximum Cuff Height	0.5~ 6.0mm
Minimum and Maximum diameter at the abutment/implant interface	∅3.8mm~∅8.0mm
Minimum Thickness	0.4 mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4 ~7 mm

TruBase S

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.

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 (Astra Tech OsseoSpeed, Astra Tech Fixture MicroMacro: X-small, Small, Large and Dentium Company Limited Implantium: Regular and PrimaConnex™ Internal Connection Implant System: 3.5, 4.1, 5.0 and Straumann Ø2.9 mm Bone Level Tapered Implants: Small Crossfit (SC) and Straumann® Bone Level Tapered Implants: Narrow Crossfit (NC), Regular Crossfit (RC) and Xpeed AnyRidge Internal Implant System: 4.0, 4.4, 4.9, 5.4, 5.9 (3.5).

CAD/CAM customized superstructure that composes the final abutment must be designed and milled through the 3Shape Abutment Designer Software, 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.

The following table shows the subject device abutment platform sizes for each of the OEM implant lines and sizes.

TruAbutment Platform Diameter / Compatible Implant System	**TruBase Engaging**	**TruBase Non-Engaging**
Astra Tech OsseoSpeed (K101732, K024111)		
X-small	o	o
Small	o	o
Large	o	o
Dentium SuperLine (K041368)		
Regular	o	o

TruAbutment Platform Diameter / Compatible Implant System	TruBase Engaging	TruBase Non-Engaging
Keystone PrimaConnex (K051614)		
3.5 (SD)	o	o
4.1 (RD)	o	o
5.0 (WD)	o	o
Straumann Bone Level (K162890) (K140878)		
SC	o	o
NC	o	o
RC	o	o
Megagen AnyRidge (K140091)		
3.5	o	o

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.

Software

- 3Shape Abutment Designer Software by 3Shape A/S, cleared under K151455.

Instruments

- Screwdrivers (class I – exempt devices)
- Scanbodies (class I – exempt devices)

Design Limitation for Zirconia superstructure

Design parameter	Design Limit
Minimum and Maximum abutment angle	0~15°
Minimum and Maximum Cuff Height	0.5~5 mm
Minimum and Maximum diameter at the abutment/implant interface	∅5.0mm~∅8.0mm
Minimum Thickness	0.4 mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4 ~6 mm

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:

- 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)

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.

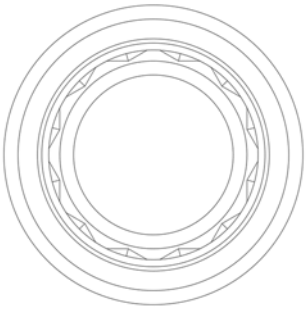
TruBase

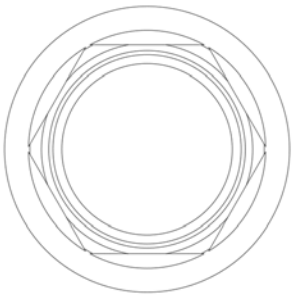
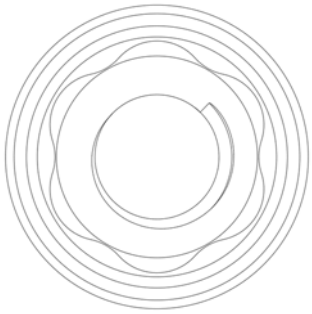
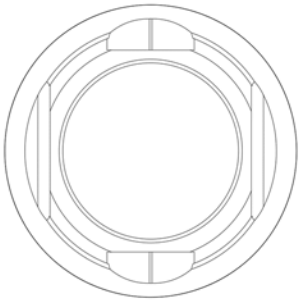
TruBase is a titanium component that is directly connected to endosseous dental implants to provide support for patient-specific prosthetic restorations, such as copings or crowns. It is indicated for a screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible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

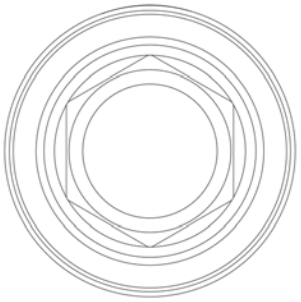
- Astra Tech Implant System (K101732), Astra Tech OsseoSpeed, Astra Tech Fixture MicroMacro (New Indication) (K024111): 3.0S, 3.5S, 4.0S, 4.5, 5.0, 5.0S (X-Small, Small, Large)
- Dentium Company Limited Implantium (K041368): 3.4, 3.8, 4.3, 4.8 (Regular)
- PrimaConnex™ Internal Connection Implant System(K051614): 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.

TruAbutment DS and TruBase are compatible with the following devices:

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
Astra Tech OsseoSpeed TX (K101732) (K024111)	3.0 S	11	24982	3.0 (X-small)	 Internal double hexagon.
		13	24983		
		15	24984		
	3.5 S	8	24930	3.5/4.0 (Small)	
		9	24931		
		11	24932		
		13	24933		
		15	24934		
		17	24935		
	4.0 S	8	24930		
		9	24931		
		11	24932		
		13	24933		
		15	24934		
		17	24935		
	4.5	9	24951	4.5/5.0 (Large)	
		11	24952		
		13	24953		
		15	24954		
		17	24955		
	5.0	9	24961		
		11	24962		
		13	24963		
		15	24964		
		17	24965		
	5.0 S	2	24971		
		11	24972		
		13	24973		
		15	24974		
		17	24975		
Dentium SuperLine (K041368)	3.4	8	FX3608SWC	Regular	
		10	FX3610SWC		
		12	FX3612SWC		
		14	FX3614SWC		
	3.8	8	FX4008SWC		
		10	FX4010SWC		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
		12	FX4012SWC		 Internal Hex
		14	FX4014SWC		
	4.3	8	FX4508SWC		
		10	FX4510SWC		
		12	FX4512SWC		
		14	FX4514SWC		
	4.8	8	FX5008SWC		
		10	FX5010SWC		
		12	FX5012SWC		
		14	FX5014SWC		
	4.8	8	FX6008SWC		
		10	FX6010SWC		
		12	FX6012SWC		
Keystone PrimaConnex (K051614)	3.5	10	15413K	3.5 (SD)	 Internal TiLobe
		11.5	15414K		
		13	15415K		
		15	15416K		
	4.1	10	15417K	4.1 (RD)	
		11.5	15418K		
		13	15419K		
		15	15415K		
	5.0	10	15421K	5.0 (WD)	
		11.5	15422K		
		13	15423K		
		15	15424K		
Straumann Bone Level Tapered Implants SC (K162890)	2.9	10	021.0010	Small Crossfit (SC)	 Internal Cross Fit®
		12	021.0112		
		14	021.0114		
Straumann Bone Level Tapered Implants NC, RC (K140878)	3.3	8	021.3508	Narrow Crossfit (NC)	
		10	021.3510		
		12	021.3512		
		14	021.3514		
		16	021.3516		
		18	021.3518		
	4.1	8	021.5508		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
		10	021.5510	Regular Crossfit (RC)	
		12	021.5512		
		14	021.5514		
		16	021.5516		
		18	021.5518		
	4.8	8	021.7508		
		10	021.7510		
		12	021.7512		
		14	021.7514		
		16	021.7516		
		18	021.7518		
Megagen AnyRidge® (K140091)	4.0	7	FANIHX3507C	3.5	 Internal Hex
		8	FANIHX3508C		
		10	FANIHX3510C		
		11.5	FANIHX3511C		
		13	FANIHX3513C		
		15	FANIHX3515C		
	4.4	7	FANIHX4007C		
		8	FANIHX4008C		
		10	FANIHX4010C		
		11.5	FANIHX4011C		
		13	FANIHX4013C		
		15	FANIHX4015C		
	4.9	7	FANIHX4508C		
		8	FANIHX4508C		
		10	FANIHX4510C		
		11.5	FANIHX4511C		
		13	FANIHX4513C		
		15	FANIHX4515C		
	5.4	7	FANIHX5007C		
		8	FANIHX5008C		
		10	FANIHX5010C		
		11.5	FANIHX5011C		
		13	FANIHX5013C		
		15	FANIHX5015C		
	5.9	7	FANIHX5507C		
		8	FANIHX5508C		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
		10	FANIHX5510C		
		11.5	FANIHX5511C		
		13	FANIHX5513C		
		15	FANIHX5515C		

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 individual 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 (K201197)
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: 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) 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: Zimmer 3.1mmD Dental Implant System (K142082) Screw Vent® and Tapered Screw Vent® (K013227) Nobel Active 3.0 (K102436) Nobel Active Internal Connection Implant (K071370) 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 compatible with the following devices: Zimmer 3.1mmD Dental Implant System(K142082) Implant Body Diameter 3.1/ Implant Platform Diameter 2.9 / Internal Hex Screw Vent® and Tapered Screw Vent® (K013227)

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruAbutment DS	TruAbutment DS (K201197)
		Implant Body Diameter 3.7/ Implant Platform Diameter 3.5 / Internal Hex Implant Body Diameter 4.1/ Implant Platform Diameter 3.5 / Internal Hex Implant Body Diameter 4.7/ Implant Platform Diameter 4.5 / Internal Hex Implant Body Diameter 6.0/ Implant Platform Diameter 5.7 / Internal Hex Nobel Active 3.0 (K102436) Implant Body Diameter 3.0/ Implant Platform Diameter 3.0 / Internal Hex Nobel Active Internal Connection Implant (K071370) Implant Body Diameter 3.5/ Implant Platform Diameter NP / Internal Hex Implant Body Diameter 4.3/ Implant Platform Diameter RP / Internal Hex Implant Body Diameter 5.0/ Implant Platform Diameter RP / Internal Hex Implant Body Diameter 5.5/ Implant Platform Diameter WP / Internal Hex
CAD Design Limits	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	Minimum and Maximum abutment angle: 0~25º Minimum and Maximum Gingival (Cuff) Height: 0.5~4.0mm Minimum and Maximum diameter at abutment/implant interface: ∅3.8~∅5.5 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): 4~8mm

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruAbutment DS	TruAbutment DS (K201197)
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 S (K201197)
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 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,	TruBase S is a titanium component that is directly connected to endosseous dental implants to provide support for custom 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: Zimmer 3.1mmD Dental Implant System (K142082) Screw Vent® and Tapered Screw Vent® (K013227) TruBase S is intended to be sent to a TruAbutment-

	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.	validated milling center for manufacture. TruBase S is compatible with the following devices: Zimmer 3.1mmD Dental Implant System(K142082) Implant Body Diameter 3.1/ Implant Platform Diameter 2.9 / Internal Hex Screw Vent® and Tapered Screw Vent® (K013227) Implant Body Diameter 3.7/ Implant Platform Diameter 3.5 / Internal Hex Implant Body Diameter 4.1/ Implant Platform Diameter 3.5 / Internal Hex Implant Body Diameter 4.7/ Implant Platform Diameter 4.5 / Internal Hex Implant Body Diameter 6.0/ Implant Platform Diameter 5.7 / Internal Hex
CAD Design Limits	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	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
Material of Abutment	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. Provided tables are comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference devices.

The Indications for Use Statement (IFUS) for the subject device (TruAbutment DS) is substantially equivalent in intended use to the primary predicate device (K201197). 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 (K201197). 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 (K201197) are related to the compatible OEM implant lines and the implant platform diameter.

The difference between the two products (TruAbutment DS, K201197) in the design parameters are the same except for the minimum diameter. The minimum diameter of the product compatible with the subject device is larger than the Primary predicate device (K201197). The diameter of the primary predicate device (K201197) is ∅3.5mm ~ ∅8.0mm, while the subject device (TruAbutment DS) can be designed up ∅3.8mm~∅8.0mm. The minor differences between the subject device (TruAbutment DS) and the primary predicate device (K201197) are related to the compatible OEM implant lines and the implant platform diameter.

Design parameter	Subject Device (TruAbutment DS) Design Limit	Primary Predicate Device (K201197) Design Limit
Minimum and Maximum abutment angle	0~25°	0~25°
Minimum and Maximum Gingival (Cuff) Height	0.5~6.0mm	0.5~6.0mm
Minimum and Maximum diameter at the abutment/implant interface	∅3.8mm~∅8.0mm	∅3.5mm~∅8.0mm
Minimum and Maximum length of the abutment	6~11mm	6~11mm
Minimum wall thickness at abutment/implant interface	0.4 mm	0.4 mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4~7mm	4~7mm

The following subject device (TruBase) is substantially equivalent in indications and design principles to the primary predicate device(K201197). The subject device (TruBase) and the primary predicate device(K201197) have internal implant interface connections, and are made of Ti-6Al-4V (abutments and abutment screws).

The subject devices (TruAbutment DS, TruBase) are to be sterilized by the end-user, the same as primary predicate devices (K201197).
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 (K201197).

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 predicate device (K152559, K170259) 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: Root-form 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 device. Therefore, TruAbutment DS, TruBase, and its predicate are substantially equivalent.