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

Re: K213961
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: June 10, 2022
Received: June 17, 2022

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213961

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:

• Straumann Tissue Level Implant (K122855, K202942): 4.1(RN), 4.8(RN), 6.5(WN) mm

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213961

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 a screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible with the following systems:

- Osstem TSIII SA (K121995) 3.5 (3.7) , 4.0 (4.2) , 4.5 (4.6) , 5.0 (5.1) , 6.0 (6.0) , 7.0 (6.8) mm (Mini, Regular)
- Astra OsseoSpeed EV (K120414) 3.6, 4.2, 4.8, 5.4 mm
- BioHorizon Tapered Internal(K093321, K143022, K071638) 3.0, 3.4, 3.8, 4.6, 5.8 mm
- Straumann Tissue Level Implant (K122855, K202942): 4.1(RN), 4.8(RN), 6.5(WN) mm

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)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary
K213961

Submitter
TruAbutment Inc.
Kiyoon Nam
17666 Fitch,
Irvine, CA 92614
USA
Email: kiyoon.nam@truabutment.com
Phone: 1-714-956-1488

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TruAbutment Inc.
Chris Choi
17666 Fitch,
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USA
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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: 07/13/2022

Predicate Devices/ Reference Devices:

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

Primary Predicate:

- TruAbutment DS (K203649) by TruAbutment Inc.

Reference Devices for OEM Compatibilities:

- Osstem TS Fixture System(K121995) by Osstem Implant Co., Ltd.
- Astra OsseoSpeed EV (K120414) by Astra.
- Biohorizons Laser-Lok 3.0 Implant System (K093321) by Biohorizons Implant Systems, Inc.
- Biohorizons Tapered Internal Implants (K143022) by Biohorizons Implant Systems, Inc.
- Biohorizons Tapered Internal Implant System (K071638) by Biohorizons Implant Systems, Inc.
- Straumann Tissue Level Implant (K122855) by Straumann USA.
- Straumann 4mm Short Implants (K202942) 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)	5.2 ~ 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 a various prosthetic platform diameters (OSSTEM TSIII SA 3.5 (3.7), 4.0 (4.2), 4.5 (4.6), 5.0 (5.1), 6.0 (6.0), 7.0 (6.8) (Mini, Regular) and Astra EV 3.6, 4.2, 4.8, 5.4mm and BioHorizons Internal 3.0, 3.5, 4.5, 5.7mm and Straumann Tissue Level: 4.1(RN), 4.8(RN), 6.5(WN). The TruBase Screws are composed of titanium alloy per ASTM F136.

CAD/CAM customized superstructure that composes the final abutment 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 abutment angle	0~15°
Minimum and Maximum Cuff Height	0.5~5 mm
Minimum and Maximum diameter at abutment/implant interface	∅6.5mm~∅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:

- Straumann Tissue Level Implant (K122855, K202942): 4.1(RN), 4.8(RN), 6.5(WN) mm

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.

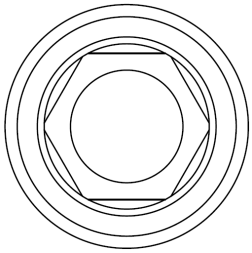
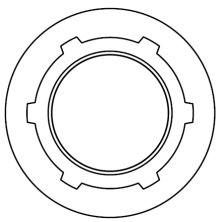
TruBase

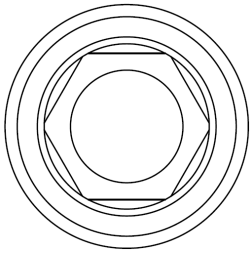
TruBase is a titanium component that is directly connected to endosseous dental implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible with the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

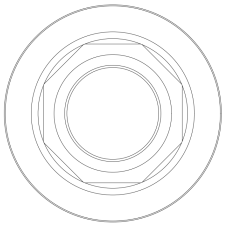
- Osstem TSIII SA (K121995): 3.5 (3.7), 4.0 (4.2), 4.5 (4.6), 5.0 (5.1), 6.0 (6.0), 7.0 (6.8) (Mini, Regular)
- Astra OsseoSpeed EV(K120414) 3.6, 4.2, 4.8, 5.4 mm
- BioHorizons Tapered Internal (K093321, K143022, K071638) 3.0, 3.4, 3.8, 4.6, 5.8 mm
- Straumann Tissue Level Implant (K122855, K202942): 4.1(RN), 4.8(RN), 6.5(WN) mm

All digitally designed zirconia superstructure for use with 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
OSSTEM TSIII SA (K121995)	3.5 (3.7)	8.5mm	TS3M3508S	2.1 (Mini)	 Internal Hex
		10mm	TS3M3510S		
		11.5mm	TS3M3511S		
		13mm	TS3M3015S		
	4.0 (4.2)	7mm	TS3S4007S	2.5 (Regular)	
		8.5mm	TS3S4008S		
		10mm	TS3S4010S		
		11.5mm	TS3S4011S		
		13mm	TS3S4013S		
	4.5 (4.6)	7mm	TS3S4507S		
		8.5mm	TS3S4508S		
		10mm	TS3S4510S		
		11.5mm	TS3S4511S		
		13mm	TS3S4513S		
	5.0 (5.1)	7 mm	TS3S5007S		
		8.5 mm	TS3S5008S		
		10 mm	TS3S5010S		
		11.5 mm	TS3S5011S		
		13 mm	TS3S5013S		
	6.0 (6.0)	7 mm	TS3S6007S		
		8.5 mm	TS3S6008S		
		10 mm	TS3S6010S		
		11.5 mm	TS3S6011S		
		13 mm	TS3S6013S		
	7.0 (6.8)	7 mm	TS3S7007S		
		8.5 mm	TS3S7008S		
		10 mm	TS3S7010S		
		11.5 mm	TS3S7011S		
		13 mm	TS3S7013S		
Astra OsseoSpeed EV (K120414)	3.6	6mm	25221	3.6	 Internal Spline
		8mm	25222		
		9mm	25223		
		11mm	25224		
		13mm	25225		
		15mm	25226		
		17mm	25227		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
	4.2	6mm	25231	4.2	
		8mm	25232		
		9mm	25233		
		11mm	25234		
		13mm	25235		
		15mm	25236		
		17mm	25237		
	4.8	6mm	25241	4.8	
		8mm	25242		
		9mm	25243		
		11mm	25244		
		13mm	25245		
		15mm	25246		
		17mm	25247		
	5.4	6mm	25251	5.4	
		8mm	25252		
		9mm	25253		
		11mm	25254		
		13mm	25255		
		15mm	25256		
BioHorizons Tapered Internal (K093321, K143022, K071638)	3.0	10.5mm	TLX3010	3.0	 Internal Hex
		12mm	TLX3012		
		15mm	TLX3015		
	3.4	9mm	TLX3409	3.0	
		10.5mm	TLX3410		
		12mm	TLX3412		
		15mm	TLX3415		
		18mm	TLX3418		
	3.8	9mm	TLX3809	3.5	
		10.5mm	TLX3810		
		12mm	TLX3812		
		15mm	TLX3815		
		18mm	TLX3818		
	4.6	7.5mm	TLX4607	4.5	
		9mm	TLX4609		
		10.5mm	TLX4610		
		12mm	TLX4612		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
		15mm	TLX4615		
		18mm	TLX4618		
	5.8	7.5mm	TLX5807	5.7	
		9mm	TLX5809		
		10.5mm	TLX5810		
		12mm	TLX5812		
		15mm	TLX5815		
		18mm	TLX5818		
Straumann Tissue Level (K122855, K202942)	4.1	6mm	033.560S	Regular Neck (RN)	Internal octagon 
		8mm	033.561S		
		10mm	033.562S		
		12mm	033.563S		
		14mm	033.564S		
	4.8	6mm	033.590S		
		8mm	033.591S		
		10mm	033.592S		
		12mm	033.593S		
		14mm	033.594S		
	6.5	6mm	033.610S	Wide Neck (WN)	
		8mm	033.611S		
		10mm	033.612S		
		12mm	033.613S		

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 (K203649)
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: Straumann Tissue Level Implant (K122855, K202942) : 4.1(RN), 4.8(RN), 6.5(WN) mm 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: 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.

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruAbutment DS	TruAbutment DS (K203649)
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): 5.2~8.0 Minimum wall thickness: 0.4 Minimum and Maximum length of abutment post (length above the abutment collar/gingival height(mm): 4.0~7.0	Minimum and Maximum abutment angle(°): 0~25 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
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	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	Predicate Device
Trade Name	TruBase	TruBase (K203649)
Indications for Use	TruBase 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: • Osstem TSIII SA (K121995): 3.5 (3.7), 4.0 (4.2), 4.5 (4.6), 5.0 (5.1), 6.0 (6.0), 7.0 (6.8) (Mini, Regular) • Astra OsseoSpeed EV(K120414) 3.6, 4.2, 4.8, 5.4 mm • BioHorizons Tapered Internal (K093321, K143022, K071638) 3.0, 3.4, 3.8, 4.6, 5.8 mm • Straumann Tissue Level Implant (K122855, K202942): 4.1(RN), 4.8(RN), 6.5 (WN) mm All digitally designed zirconia superstructure for use with 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 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.
CAD Design Limits	Maximum Angulation 0~15° Maximum Cuff Height 0.5~5mm Minimum Diameter Ø 5.0~ Ø 8.0mm Minimum Thickness 0.4mm Minimum Post Height 4~6mm	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

Attributes	Proposed Device	Predicate Device
Trade Name	TruBase	TruBase (K203649)
		Minimum post height(mm): 4~6
Material of Abutment and Screw	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)
Manufacturing processes	TruAbutment-validated milling center	TruAbutment-validated milling center
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 (K203649). 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 (K203649) 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 (K203649) 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(K203649) listed above. The subject device (TruBase) and the primary predicate device(K203649) 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 (K203649). 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 (K203649).

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 predicate device (K203649) 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.

Non-clinical worst-case MRI review was performed to evaluate the metallic TruAbutment and TruBase devices 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."

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.