October 9, 2024

TruAbutment Inc.
Ki Yoon Nam
RA Senior Manager
17666 Fitch
Irvine, California 92614

Re: K241485
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: September 12, 2024
Received: September 12, 2024

Dear Ki Yoon Nam:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241485

Device Name

TruAbutment DS; TruBase

Indications for Use *(Describe)*

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

• Astra OsseoSpeed EV (K130999, K120414)
: 3.0, 3.6, 4.2, 4.8, 5.4 mm.
• Biomet 3i Full OSSEOTITE Tapered Certain (K130949)
: 3.25, 4.0, 5.0, 6.0 mm.
• DIO UF (II) Internal Submerged (K161987, K170608, K173975)
: 3.3, 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0 (Narrow, Regular) mm.
• Neoss ProActive® (K083561)
: 3.25, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 (NP, SP) mm.
• Osstem TS (K161604)
: 3.0, 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) mm.
• Camlog Screw-Line (K083496)
: 3.3, 3.8, 4.3, 5.0, 6.0 mm.
• Conelog Screw-Line (K113779)
: 3.3, 3.8, 4.3, 5.0 mm.
• Implant Direct Legacy2 (K192221)
: 3.2 mm.
• BioHorizons Internal Implant System (K093321, K143022, K071638)
: 3.0, 3.4, 3.8, 4.6, 5.8 mm.
• MegaGen AnyRidge Internal Implant (K140091)
: 3.5, 4.0, 4.5, 5.0, 5.5 (3.5) mm.

All digitally designed abutments and/or copings 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 OsseoSpeed EV (K130999): 3.0 mm.
• Biomet 3i Full OSSEOTITE Tapered Certain (K130949): 3.25, 4.0, 5.0, 6.0 mm.
• DIO UF(II) Internal Submerged (K161987, K170608, K173975): 3.3, 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0 (Narrow, Regular) mm.
• Neoss ProActive® (K083561): 3.25, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 (NP, SP) mm.
• Camlog Screw-Line (K083496): 3.3, 3.8, 4.3, 5.0, 6.0 mm.
• Conelog Screw-Line (K113779): 3.3, 3.8, 4.3, 5.0 mm.
• Implant Direct Legacy2 (K192221): 3.2 mm.
All digitally designed abutments and/or copings 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.

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510(k) Summary
K241485

Submitter
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Device Information

- Trade Name: TruAbutment DS, TruBase
- 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
- Date prepared: 10/09/2024.

Primary Predicate / Reference Devices:

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

Primary Predicate:

- TruAbutment DS (K203649) by TruAbutment Inc.

Reference Devices for OEM Compatibilities:

- Astra OsseoSpeed EV (K130999, K120414) by Astra Tech, Inc.
- Biomet 3i Full OSSEOTITE Tapered Certain (K130949) by Zimmer Biomet.
- DIO UF (II) Internal Submerged (K161987, K170608, K173975) by DIO Implant Co., Ltd.
- Neoss ProActive® (K083561) by Neoss Limited.
- Camlog Screw-Line (K083496) by CAMLOG Biotechnologies GmbH.
- Conelog Screw-Line (K113779) by CAMLOG Biotechnologies GmbH.
- Osstem TS Fixture System (K161604) by Osstem Implant Co., Ltd.
- BioHorizons Laser-Lok 3.0 Implant System (K093321) by Biohorizons Implant Systems, Inc.

- Biohorizons Tapered Internal Implant System (K143022) by Biohorizons Implant Systems, Inc.
- Biohorizons Tapered Internal Implant System (K071638) by Biohorizons Implant Systems, Inc.
- Xpeed AnyRidge Internal Implant System (K140091) by MegaGen Implant Co., Ltd.
- Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts (K192221) by Implant Direct LLC.

General Description

TruAbutment DS, TruBase and abutment screw are made of Titanium grade Ti-6A1-4V ELI (meets ASTM Standard F136). TruAbutment DS, TruBase are supplied with two identical screws which are used:

(1) For fixing the abutment into the endosseous implant.
(2) For dental laboratory use during construction of related restoration.

TruAbutment DS, TruBase are provided non-sterile. Therefore, it must be sterilized before use.

TruAbutment DS, TruBase are devices that can only be sold, distributed, or used upon the order of an authorized healthcare provider, generally referred to as prescription (Rx) devices.

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 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	TruBase Engaging	TruBase Non-Engaging
Astra OsseoSpeed EV				
3.0	x	o	o	o
3.6	x	o	x	x
4.2	x	o	x	x
4.8	x	o	x	x
5.4	x	o	x	x
Biomet 3i Full OSSEOTITE Tapered Certain				
3.4	x	o	o	o
4.1	x	o	o	o
5.0	x	o	o	o
6.0	x	o	o	o
DIO UF (II) Internal				
Narrow	x	o	o	o
Regular	x	o	o	o
Neoss ProActive®				
NP	x	o	o	o
SP	x	o	o	o
Camlog Screw-Line				
3.3	o	o	o	o
3.8	o	o	o	o

4.3	o	o	o	o
5.0	o	o	o	o
6.0	o	o	o	o
Conelog Screw-Line				
3.3	o	o	o	o
3.8	o	o	o	o
4.3	o	o	o	o
5.0	o	o	o	o
Implant Direct Legacy2				
3.2	o	o	o	o
Osstem TS				
Mini	x	o	x	x
Regular	x	o	x	x
BioHorizons Internal				
3.0	x	o	x	x
3.5	x	o	x	x
4.5	x	o	x	x
5.7	x	o	x	x
MegaGen Xpeed AnyRidge Internal				
3.5	x	o	x	x

X: Not included in this submission

O: Included in this submission

TruAbutment DS

TruAbutment DS system includes patient-specific abutments that 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 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.

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)	3.3 ~ 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 is a two-piece abutment. The base component is premanufactured and is used to support a cemented CAD/CAM zirconia superstructure. The base and the zirconia superstructure together form the final abutment.

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.

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, which is directly connected to endosseous dental implants and is intended to be used as an aid in prosthetic rehabilitation. It is compatible with the following systems:

- Astra OsseoSpeed EV (K130999, K120414)
  : 3.0, 3.6, 4.2, 4.8, 5.4 mm.
- Biomet 3i Full OSSEOTITE Tapered Certain (K130949)
  : 3.25, 4.0, 5.0, 6.0 mm.
- DIO UF (II) Internal Submerged (K161987, K170608, K173975)
  : 3.3, 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0 (Narrow, Regular) mm.
- Neoss ProActive® (K083561)
  : 3.25, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 (NP, SP) mm.
- Osstem TS (K161604)
  : 3.0, 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) mm.
- Camlog Screw-Line (K083496)
  : 3.3, 3.8, 4.3, 5.0, 6.0 mm.
- Conelog Screw-Line (K113779)
  : 3.3, 3.8, 4.3, 5.0 mm.
- Implant Direct Legacy2 (K192221)
  : 3.2 mm.
- BioHorizons Internal Implant System (K093321, K143022, K071638)
  : 3.0, 3.4, 3.8, 4.6, 5.8 mm.
- MegaGen AnyRidge Internal Implant (K140091)
  : 3.5, 4.0, 4.5, 5.0, 5.5 (3.5) mm.

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

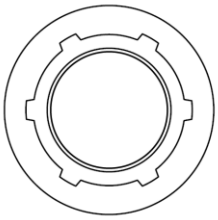
TruBase

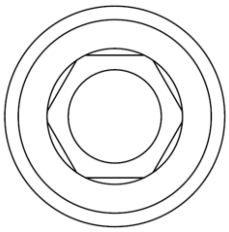
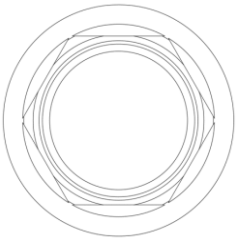
TruBase is a titanium component that is directly connected to endosseous dental implants to provide support for patient-specific prosthetic restorations, such as copings or crowns. It is indicated for a screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible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

- Astra OsseoSpeed EV (K130999): 3.0 mm.
- Biomet 3i Full OSSEOTITE Tapered Certain (K130949): 3.25, 4.0, 5.0, 6.0 mm.
- DIO UF(II) Internal Submerged (K161987, K170608, K173975): 3.3, 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0 (Narrow, Regular) mm.
- Neoss ProActive® (K083561): 3.25, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 (NP, SP) mm.
- Camlog Screw-Line (K083496): 3.3, 3.8, 4.3, 5.0, 6.0 mm.
- Conelog Screw-Line (K113779): 3.3, 3.8, 4.3, 5.0 mm.
- Implant Direct Legacy2 (K192221): 3.2 mm.

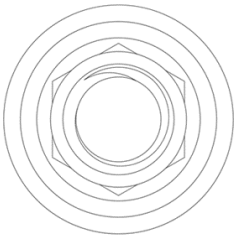
All digitally designed abutments and/or copings for use with the TruAbutment DS abutments are intended to be sent to a TruAbutment-validated milling center for manufacture.

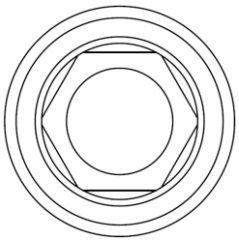
TruAbutment DS and TruBase are compatible with the following OEM devices:

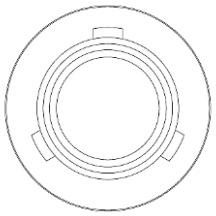
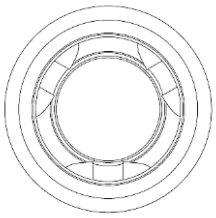
Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
Astra OsseoSpeed EV (K130999) (K120414)	3.0	8	26301	3.0	 Internal Spline connection "Index System"
		9	26302		
		11	26303		
		13	26304		
		15	26305		
	3.6	6	26310	3.6	
		8	26311		
		9	26312		
		11	26313		
		13	26314		
		15	26315		
		17	26316		
	4.2	6	26320	4.2	
		8	26321		
		9	26322		
		11	26323		
		13	26324		
		15	26325		
		17	26326		
	4.8	6	26340	4.8	
		8	26341		
		9	26342		
		11	26343		
		13	26344		
		15	26345		
		17	26346		
	5.4	6	26360	5.4	
		8	26361		
		9	26362		
		11	26363		
		13	26364		
		15	26365		
	3.25	8.5	IFNT3285	3.4	

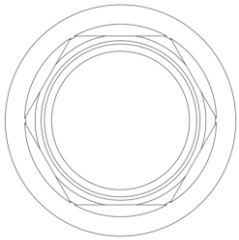
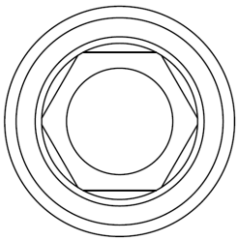
Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
Biomet 3i Full OSSEOTITE Tapered Certain (K130949)		10	IFNT3210		 Internal Hex Connection
		11.5	IFNT3211		
		13	IFNT3213		
		15	IFNT3215		
	4.0	8.5	IFNT485	4.1	
		10	IFNT410		
		11.5	IFNT411		
		13	IFNT413		
		15	IFNT415		
	5.0	8.5	IFNT585	5.0	
		10	IFNT510		
		11.5	IFNT511		
		13	IFNT513		
		15	IFNT515		
	6.0	8.5	IFNT685	6.0	
		10	IFNT610		
		11.5	IFNT611		
		13	IFNT613		
		15	IFNT615		
DIO UF (II) Internal Submerged Implant (K161987) (K170608) (K173975)	3.3	8.5	UF(II)N 3308S	Narrow (K161987)	 Internal Hex Connection
		10	UF(II)N 3310S		
		11.5	UF(II)N 3311S		
		13	UF(II)N 3313S		
		15	UF(II)N 3315S		
	3.8	8.5	UF(II) 3808S	Regular (K170608)	
		10	UF(II) 3810S		
		11.5	UF(II) 3811S		
		13	UF(II) 3813S		
		15	UF(II) 3815S		
		16	UF(II) 3816S		
	4.0	7	UF(II) 4007S		
		8.5	UF(II) 4008S		
		10	UF(II) 4010S		
		11.5	UF(II) 4011S		
		13	UF(II) 4013S		
		15	UF(II) 4015S		

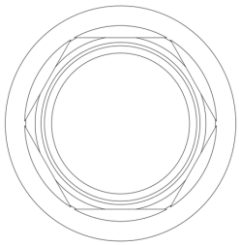
Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
		16	UF(II) 4016S		
	4.5	7	UF(II) 4507S		
		8.5	UF(II) 4508S		
		10	UF(II) 4510S		
		11.5	UF(II) 4511S		
		13	UF(II) 4513S		
		15	UF(II) 4515S		
		16	UF(II) 4516S		
	5.0	7	UF(II) 5007S		
		8.5	UF(II) 5008S		
		10	UF(II) 5010S		
		11.5	UF(II) 5011S		
		13	UF(II) 5013S		
		15	UF(II) 5015S		
		16	UF(II) 5016S		
	5.5	7	UF(II) 5507S		
		8.5	UF(II) 5508S		
		10	UF(II) 5510S		
		11.5	UF(II) 5511S		
		13	UF(II) 5513S		
		15	UF(II) 5515S		
		16	UF(II) 5516S		
	6.0	7	UF(II) 6007S	Wide (K173975)	
		8.5	UF(II) 6008S		
		10	UF(II) 6010S		
		11.5	UF(II) 6011S		
		13	UF(II) 6013S		
	6.5	7	UF(II) 6507S		
		8.5	UF(II) 6508S		
		10	UF(II) 6510S		
		11.5	UF(II) 6511S		
		13	UF(II) 6513S		
	7.0	7	UF(II) 7007S		
		8.5	UF(II) 7008S		
		10	UF(II) 7010S		
		11.5	UF(II) 7011S		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
		13	UF(II) 7013S		
Neoss ProActive® (K083561)	3.25	9	21176	3.5 (NP)	 Internal Hex Connection
		11	21177		
		13	21178		
		15	21179		
	3.5	7	21181	4.0 (SP)	
		9	21182		
		11	21183		
		13	21184		
		15	21185		
		17	21186		
	4.0	7	21187		
		9	21188		
		11	21189		
		13	21190		
		15	21191		
		17	21192		
	4.5	7	21193		
		9	21194		
		11	21195		
		13	21196		
		15	21197		
		17	21198		
	5.0	7	21199		
		9	21200		
		11	21201		
		13	21202		
		15	21203		
		17	21205		
	5.5	9	21206		
		11	21207		
		13	21208		
		15	21211		
	6.0	9	21212		
		11	21213		
		13	21221		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
		15	21222		
OSSTEM TS (K161604)	3.0	8.5	TS3M3008S	2.1 (Mini)	 Internal Hex connection
		10	TS3M3010S		
		11.5	TS3M3011S		
		13	TS3M3013S		
	3.5 (3.7)	8.5	TS3M3508S		
		10	TS3M3510S		
		11.5	TS3M3511S		
		13	TS3M3513S		
	4.0 (4.2)	7	TS3S4007S	2.5 (Regular)	
		8.5	TS3S4008S		
		10	TS3S4010S		
		11.5	TS3S4011S		
		13	TS3S4013S		
	4.5 (4.6)	7	TS3S4507S		
		8.5	TS3S4508S		
		10	TS3S4510S		
		11.5	TS3S4511S		
		13	TS3S4513S		
	5.0 (5.1)	7	TS3S5007S		
		8.5	TS3S5008S		
		10	TS3S5010S		
		11.5	TS3S5011S		
		13	TS3S5013S		
	6.0 (6.0)	7	TS3S6007S		
		8.5	TS3S6008S		
		10	TS3S6010S		
		11.5	TS3S6011S		
		13	TS3S6013S		
	7.0 (6.8)	7	TS3S7007S		
		8.5	TS3S7008S		
		10	TS3S7010S		
		11.5	TS3S7011S		
		13	TS3S7013S		
	3.3	11	K1046.3311	3.3	
		13	K1046.3313		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
Camlog Screw-Line (K083496)		16	K1046.3316		 Tube-in-tube connection
	3.8	9	K1046.3809	3.8	
		11	K1046.3811		
		13	K1046.3813		
		16	K1046.3816		
	4.3	9	K1046.4309	4.3	
		11	K1046.4311		
		13	K1046.4313		
		16	K1046.4316		
	5.0	9	K1046.5009	5.0	
		11	K1046.5011		
		13	K1046.5013		
		16	K1046.5016		
	6.0	9	K1046.6009	6.0	
		11	K1046.6011		
		13	K1046.6013		
		16	K1046.6016		
Conelog Screw-Line (K113779)	3.3	9	C1065.3309	3.3	 Conical abutment connectoin
		11	C1065.3311		
		13	C1065.3313		
		16	C1065.3316		
	3.8	7	C1065.3807	3.8	
		9	C1065.3809		
		11	C1065.3811		
		13	C1065.3813		
		16	C1065.3816		
	4.3	7	C1065.4307	4.3	
		9	C1065.4309		
		11	C1065.4311		
		13	C1065.4313		
		16	C1065.4316		
	5.0	7	C1065.5007	5.0	
		9	C1065.5009		
		11	C1065.5011		
		13	C1065.5013		
		16	C1065.5016		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
Implant Direct Legacy2 (K192221)	3.2	8	823208	3.0	 Internal Hex Connection
		10	823210		
		11.5	823211		
		13	823213		
		16	823216		
BioHorizons Laser-Lok (K093321)	3.0	10.5	TLX3010	3.0	
		12	TLX3012		
		15	TLX3015		
BioHorizons Tapered Internal (K071638) (K143022)	3.4	9	TLX3409	3.0	 Internal Hex Connection
		10.5	TLX3410		
		12	TLX3412		
		15	TLX3415		
		18	TLX3418		
	3.8	9	TLX3809	3.5	
		10.5	TLX3810		
		12	TLX3812		
		15	TLX3815		
		18	TLX3818		
	4.6	7.5	TLX4607	4.5	
		9	TLX4609		
		10.5	TLX4610		
		12	TLX4612		
		15	TLX4615		
		18	TLX4618		
	5.8	7.5	TLX5807	5.7	
		9	TLX5809		
		10.5	TLX5810		
		12	TLX5812		
		15	TLX5815		
		18	TLX5818		
		7	FANIHX3507C		
		8	FANIHX3508C		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
MegaGen Xpeed AnyRidge® (K140091)	3.5	10	FANIHX3510C	3.5	 Internal Hex Connection
		11.5	FANIHX3511C		
		13	FANIHX3513C		
		15	FANIHX3515C		
		18	FANIHX3518C		
	4.0	7	FANIHX4007C		
		8	FANIHX4008C		
		10	FANIHX4010C		
		11.5	FANIHX4011C		
		13	FANIHX4013C		
		15	FANIHX4015C		
		18	FANIHX4018C		
	4.5	7	FANIHX4507C		
		8	FANIHX4508C		
		10	FANIHX4510C		
		11.5	FANIHX4511C		
		13	FANIHX4513C		
		15	FANIHX4515C		
		18	FANIHX4518C		
	5.0	7	FANIHX5007C		
		8	FANIHX5008C		
		10	FANIHX5010C		
		11.5	FANIHX5011C		
		13	FANIHX5013C		
		15	FANIHX5015C		
		18	FANIHX5018C		
	5.5	7	FANIHX5507C		
		8	FANIHX5508C		
		10	FANIHX5510C		
		11.5	FANIHX5511C		
		13	FANIHX5513C		
		15	FANIHX5515C		
		18	FANIHX5518C		

Summary of Technological Characteristic

The subject base and blank devices are identical to the K203649 base and blank devices besides the compatible implant bodies.. They are substantially equivalent in intended use, the material and connection interfaces to the implants identical for each diameter and connection type. A 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: Astra OsseoSpeed EV (K130999, K120414) : 3.0, 3.6, 4.2, 4.8, 5.4 mm. Biomet 3i Full OSSEOTITE Tapered Certain (K130949) : 3.25, 4.0, 5.0, 6.0 mm. DIO UF(II) Internal Submerged (K161987, K170608, K173975) : 3.3, 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0 (Narrow, Regular) mm. Neoss ProActive® (K083561) : 3.25, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 (NP, SP) mm. Osstem TS (K161604) : 3.0, 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) mm. Camlog Screw-Line (K083496) : 3.3, 3.8, 4.3, 5.0, 6.0 mm.	The TruAbutment DS is 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) mm. Neodent Implant System – GM Helix (K163194, K180536) : 3.5, 3.75, 4.0, 4.3, 5.0 (3.0), 6.0 (3.0) mm. Nobel Biocare Groovy Implants (K050258) : 3.5, 4.3, 5.0, 6.0 (NP, RP, WP, 6.0) mm. Straumann BLX Implant (K173961, K181703, K191256) : 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB, WB) mm. Straumann Tissue Level Implant (K111357) : 3.3 (NNC) mm. All digitally designed abutments and/or copings 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)
	Conelog Screw-Line (K113779) : 3.3, 3.8, 4.3, 5.0 mm. Implant Direct Legacy2 (K192221) : 3.2 mm. BioHorizons Internal (K093321, K071638, K143022) : 3.0, 3.4, 3.8, 4.6, 5.8 mm. MegaGen AnyRidge Internal Implant (K140091) : 3.5, 4.0, 4.5, 5.0, 5.5 (3.5) mm. All digitally designed abutments and/or copings 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: Astra OsseoSpeed EV (K130999, K120414) Implant Body Diameter (mm): 3.0 /Implant Platform (mm): 3.0 / Internal Spline connection. Implant Body Diameter (mm): 3.6 /Implant Platform (mm): 3.6 / Internal Spline connection. Implant Body Diameter (mm): 4.2 /Implant Platform (mm): 4.2 / Internal Spline connection. Implant Body Diameter (mm): 4.8 /Implant Platform (mm): 4.8 / Internal Spline connection. Implant Body Diameter (mm): 5.4 /Implant Platform (mm): 5.4/ Internal Spline connection. Biomet 3i Full OSSEOTITE Tapered Certain (K130949)	

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruAbutment DS	TruAbutment DS (K203649)
	Implant Body Diameter (mm): 3.25 / Implant Platform (mm): 3.4 / Internal Hex connection. Implant Body Diameter (mm): 4.0 / Implant Platform (mm): 4.1 / Internal Hex connection. Implant Body Diameter (mm): 5.0 / Implant Platform (mm): 5.0 / Internal Hex connection. Implant Body Diameter (mm): 6.0 / Implant Platform (mm): 6.0 / Internal Hex connection. DIO UF(II) Internal Submerged (K161987, K170608, K173975) Implant Body Diameter (mm): 3.3 /Implant Platform (mm): Narrow / Internal Hex connection. Implant Body Diameter (mm): 3.8 /Implant Platform (mm): Regular / Internal Hex connection. Implant Body Diameter (mm): 4.0 /Implant Platform (mm): Regular / Internal Hex connection. Implant Body Diameter (mm): 4.5 /Implant Platform (mm): Regular / Internal Hex connection. Implant Body Diameter (mm): 5.0 /Implant Platform (mm): Regular / Internal Hex connection. Implant Body Diameter (mm): 5.5 /Implant Platform (mm): Regular / Internal Hex connection. Implant Body Diameter (mm): 6.0 /Implant Platform (mm): Wide / Internal Hex connection. Implant Body Diameter (mm): 6.5 /Implant Platform (mm): Wide / Internal Hex connection. Implant Body Diameter (mm): 7.0 /Implant Platform (mm):	

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruAbutment DS	TruAbutment DS (K203649)
	Wide / Internal Hex connection. Neoss ProActive® (K083561) Implant Body Diameter (mm): 3.25 / Implant Platform (mm): 3.5 / Internal Hex connection. Implant Body Diameter (mm): 3.5 /Implant Platform (mm): 4.0 / Internal Hex connection. Implant Body Diameter (mm): 4.0 /Implant Platform (mm): 4.0 / Internal Hex connection. Implant Body Diameter (mm): 4.5 /Implant Platform (mm): 4.0 / Internal Hex connection. Implant Body Diameter (mm): 5.0 /Implant Platform (mm): 4.0 / Internal Hex connection. Implant Body Diameter (mm): 5.5 /Implant Platform (mm): 4.0 / Internal Hex connection. Implant Body Diameter (mm): 6.0 /Implant Platform (mm) 4.0 / Internal Hex connection. Osstem TS (K161604) Implant Body Diameter (mm): 3.0 / Implant Platform (mm): 2.1 / Internal Hex connection. Implant Body Diameter (mm): 3.5 / Implant Platform (mm): 2.1 / Internal Hex connection. Implant Body Diameter (mm): 4.0 / Implant Platform (mm): 2.5/ Internal Hex connection. Implant Body Diameter (mm): 4.5 / Implant Platform (mm): 2.5 / Internal Hex connection. Implant Body Diameter (mm): 5.0 / Implant Platform (mm):	

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruAbutment DS	TruAbutment DS (K203649)
	2.5 / Internal Hex connection. Implant Body Diameter (mm): 6.0 / Implant Platform (mm): 2.5 / Internal Hex connection. Implant Body Diameter (mm): 7.0 / Implant Platform (mm): 2.5 / Internal Hex connection. Camlog Screw-Line (K083496) Implant Body Diameter (mm): 3.3 / Implant Platform (mm): 3.3 / Tube-in-tube connection. Implant Body Diameter (mm): 3.8 /Implant Platform (mm): 3.8 / Tube-in-tube connection. Implant Body Diameter (mm): 4.3 /Implant Platform (mm): 4.3 / Tube-in-tube connection. Implant Body Diameter (mm): 5.0 /Implant Platform (mm): 5.0 / Tube-in-tube connection. Implant Body Diameter (mm): 6.0 /Implant Platform (mm): 6.0/ Tube-in-tube connection. Conelog Screw-Line (K113779) Implant Body Diameter (mm): 3.3 /Implant Platform (mm): 3.3 / Conical abutment connection. Implant Body Diameter (mm): 3.8 /Implant Platform (mm): 3.8 / Conical abutment connection. Implant Body Diameter (mm): 4.3 /Implant Platform (mm): 4.3 / Conical abutment connection. Implant Body Diameter (mm): 5.0 /Implant Platform (mm): 5.0 / Conical abutment connection.	

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruAbutment DS	TruAbutment DS (K203649)
	Implant Direct Legacy2 (K192221) Implant Body Diameter (mm): 3.2 /Implant Platform (mm): 3.0 / Internal Hex connection. BioHorizons Internal Implant System (K093321, K071638, K143022) Implant Body Diameter (mm): 3.0/ Implant Platform (mm): 3.0 / Internal Hex connection. Implant Body Diameter (mm): 3.4/ Implant Platform (mm): 3.0 / Internal Hex connection. Implant Body Diameter (mm): 3.8/ Implant Platform (mm): 3.5 / Internal Hex connection. Implant Body Diameter (mm): 4.6/ Implant Platform (mm): 4.5 / Internal Hex connection. Implant Body Diameter (mm): 5.8/ Implant Platform (mm): 5.7 / Internal Hex connection. MegaGen AnyRidge Internal Implant System (K140091) Implant Body Diameter (mm): 3.5/ Implant Platform (mm): 3.5 / Internal Hex connection. Implant Body Diameter (mm): 4.0/ Implant Platform (mm): 3.5 / Internal Hex connection. Implant Body Diameter (mm): 4.5/ Implant Platform (mm): 3.5 / Internal Hex connection. Implant Body Diameter (mm): 5.0/ Implant Platform (mm): 3.5 / Internal Hex connection. Implant Body Diameter (mm): 5.5/ Implant Platform (mm): 3.5 / Internal Hex connection.	

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): 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 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 (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
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 (K203649)
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: Astra OsseoSpeed EV (K130999) : 3.0 mm. Biomet 3i Full OSSEOTITE Tapered Certain (K130949) : 3.25, 4.0, 5.0, 6.0 mm. DIO UF(II) Internal Submerged (K161987, K170608, K173975) : 3.3, 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0 (Narrow, Regular) mm. Neoss ProActive® (K083561) : 3.25, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 (NP, SP) mm. Camlog Screw-Line (K083496) : 3.3, 3.8, 4.3, 5.0, 6.0 mm. Conelog Screw-Line (K113779) :3.3, 3.8, 4.3, 5.0 mm. Implant Direct Legacy2 (K192221) : 3.0 mm. All digitally designed zirconia superstructures 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 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) mm. Neodent Implant System - GM Helix (K163194, K180536) : 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0(3.0) mm. Nobel Biocare Groovy Implants (K050258) : 3.5. 4.3, 5.0, 6.0 (NP, RP, WP, 6.0) mm. Straumann BLX Implant (K173961, K181703, K191256) : 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB, WB) mm. Straumann Tissue Level Implant (K111357) : 3.3 (NNC) mm. All digitally designed zirconia superstructures for use with the TruBase are intended to be sent to a TruAbutment-validated milling center for manufacture.

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruBase	TruBase (K203649)
	TruBase is compatible with the following devices: Astra OsseoSpeed EV(K130999) Implant Body Diameter (mm): 3.0 / Implant Platform (mm): 3.0 / Internal Spline connection. Biomet 3i Full OSSEOTITE Tapered Certain (K130949) Implant Body Diameter (mm): 3.25 / Implant Platform (mm): 3.4 / Internal Hex connection. Implant Body Diameter (mm): 4.0 / Implant Platform (mm): 4.1 / Internal Hex connection. Implant Body Diameter (mm): 5.0 / Implant Platform (mm): 5.0 / Internal Hex connection. Implant Body Diameter (mm): 6.0 / Implant Platform (mm): 6.0 / Internal Hex connection. DIO UF(II) Internal Submerged (K161987, K170608, K173975) Implant Body Diameter (mm): 3.3 / Implant Platform (mm): Narrow / Internal Hex connection. Implant Body Diameter (mm): 3.8 / Implant Platform (mm): Regular/ Internal Hex connection. Implant Body Diameter (mm): 4.0 / Implant Platform (mm): Regular / Internal Hex connection. Implant Body Diameter (mm): 4.5 / Implant Platform (mm): Regular / Internal Hex connection. Implant Body Diameter (mm): 5.0 / Implant Platform (mm): Regular / Internal Hex connection. Implant Body Diameter (mm): 5.5 / Implant Platform (mm): Regular / Internal Hex connection. Implant Body Diameter (mm): 6.0 / Implant Platform (mm): Wide / Internal Hex connection.	

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruBase	TruBase (K203649)
	Implant Body Diameter (mm): 6.5 / Implant Platform (mm): Wide / Internal Hex connection. Implant Body Diameter (mm): 7.0 / Implant Platform (mm): Wide / Internal Hex connection. Neoss ProActive® (K083561) Implant Body Diameter (mm): 3.25 / Implant Platform (mm): 3.5 / Internal Hex connection. Implant Body Diameter (mm): 3.5 / Implant Platform (mm): 4.0 / Internal Hex connection. Implant Body Diameter (mm): 4.0 / Implant Platform (mm): 4.0 / Internal Hex connection. Implant Body Diameter (mm): 4.5 / Implant Platform (mm): 4.0 / Internal Hex connection. Implant Body Diameter (mm): 5.0 / Implant Platform (mm): 4.0 / Internal Hex connection. Implant Body Diameter (mm): 6.0 / Implant Platform (mm) 4.0 / Internal Hex connection. Camlog Screw-Line (K083496) Implant Body Diameter (mm): 3.3 / Implant Platform (mm): 3.3 / Tube-in-tube connection. Implant Body Diameter (mm): 3.8 / Implant Platform (mm): 3.8 / Tube-in-tube connection. Implant Body Diameter (mm): 4.3 / Implant Platform (mm): 4.3 / Tube-in-tube connection. Implant Body Diameter (mm): 5.0 / Implant Platform (mm): 5.0 / Tube-in-tube connection. Implant Body Diameter (mm): 6.0 / Implant Platform (mm): 6.0/ Tube-in-tube connection.	

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruBase	TruBase (K203649)
	Conelog Screw-Line (K113779) Implant Body Diameter (mm): 3.3 / Implant Platform (mm): 3.3 / Conical abutment connection. Implant Body Diameter (mm): 3.8 / Implant Platform (mm): 3.8 / Conical abutment connection. Implant Body Diameter (mm): 4.3 / Implant Platform (mm): 4.3 / Conical abutment connection. Implant Body Diameter (mm): 5.0 / Implant Platform (mm): 5.0 / Conical abutment connection. Implant Direct Legacy2 (K192221) Implant Body Diameter (mm): 3.2 / Implant Platform (mm): 3.0 / Internal Hex connection.	
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 length above the abutment collar/gingival height (mm): 4~6	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 length above the abutment collar/gingival height (mm): 4~6
Abutment Base and Screw Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
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)

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruBase	TruBase (K203649)
Material of Cement	RelyX Unicem 2Automix by 3M ESPE (K100756)	RelyX Unicem 2Automix by 3M ESPE (K100756)
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 listed above. The provided tables compare the Indications for Use Statements and the technological characteristics of the subject device, and 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. None of these minor differences impact substantial equivalences because all IFUS express equivalence intended to be used to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

The subject device and the predicate device indications and design parameters are identical.

Design Parameter	Subject Device (TruAbutment DS) Design Limit	Primary Predicate Device (K203649) Design Limit
Minimum and Maximum abutment angle (°)	0 ~ 25	0 ~ 25
Minimum and Maximum cuff height (mm)	0.5 ~ 6.0	0.5 ~ 6.0
Minimum and Maximum diameter at abutment/implant interface (Ø, mm)	3.3 ~ 8.0	3.3 ~ 8.0
Minimum and Maximum length of the abutment (mm)	6 ~ 11	6 ~ 11
Minimum wall thickness at abutment/implant interface (mm)	0.4	0.4 ~ 0.9
Minimum and Maximum length of abutment post (length above the abutment collar / gingival height) (mm)	4.0 ~ 7.0	4.0 ~ 7.0

The following subject device (TruBase) is substantially equivalent in indications and design principles to the primary predicate device (K203649). 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).

Design Parameter	Subject Device (TruBase) Design Limit	Primary Predicate Device (K203649) Design Limit
Minimum and Maximum angulation (°)	0 ~ 15	0 ~ 15
Minimum and Maximum gingival (cuff) height (mm)	0.5 ~ 5.0	0.5 ~ 5.0
Minimum and Maximum diameter at abutment/implant interface (Ø, mm)	5.0 ~ 8.0	5.0 ~ 8.0
Minimum thickness (mm)	0.4	0.4
Minimum and Maximum length of abutment post (length above the abutment collar / gingival height) (mm)	4.0 ~ 6.0	4.0 ~ 6.0

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.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic DS, TruBase 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 Displ acement Force and Torque on Metal Alloys Used in Medical Devices.” Journal of Testin g and Evaluation 49.2 (2019): 783-795), based on the entire system including all variatio ns (all compatible implant bodies, dental abutments, and fixation screws) and material co mposition. Rationale addressed parameters per the FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,” including ma gnetically induced displacement force and torque.

Non-clinical Testing

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

- Fatigue Test according to ISO 14801:2016

The tests below 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 substantial equivalence with the reference devices.

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

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

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

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 reference devices. Therefore, TruAbutment DS, TruBase, and predicate devices substantially equivalent.