June 19, 2020

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

Re: K191913
Trade/Device Name: TruAbutment DS
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 19, 2020
Received: May 19, 2020

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 Srinivas Nandkumar, Ph.D.
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)*
K191913

Device Name
TruAbutment DS

Indications for Use *(Describe)*
The 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:
- Biomet 3i 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 mm
- Megagen AnyRidge® (K140091) 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0 mm
- Neoss ProActive® (K083561) 3.25, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 mm

The available range of diameters is summarized below:

Biomet 3i Certain® (K130949)
- Implant Ø (mm) : 3.25 / Implant Platform (mm) : 3.4 / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 4.0 / Implant Platform (mm) : 4.1 / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 5.0 / Implant Platform (mm) : 5.0 / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 6.0 / Implant Platform (mm) : 6.0 / Type of Implant-Abutment Connection : Internal Hex

DIO UF(II) Internal Submerged (K161987, K170608, K173975)
- Implant Ø (mm) : 3.3 / Implant Platform (mm) : Narrow / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 3.8 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 4.0 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 4.5 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 5.0 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 5.5 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 6.0 / Implant Platform (mm) : Wide / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 6.5 / Implant Platform (mm) : Wide / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 7.0 / Implant Platform (mm) : Wide / Type of Implant-Abutment Connection : Internal Hex

Megagen AnyRidge® (K140091)
- Implant Ø (mm) : 3.5 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 4.0 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 4.5 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 5.0 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 5.5 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex

Neoss ProActive® (K083561)
- Implant Ø (mm) : 3.25 / Implant Platform (mm) : 3.5 / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 3.5 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 4.0 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 4.5 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 5.0 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 5.5 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex
- Implant Ø (mm) : 6.0 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex

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.

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510(k) Summary

Submitter
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Device Information

- Trade Name: TruAbutment DS,
- 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: 06/19/2020

Predicate Devices/Reference Devices

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

Primary Predicate
- TruAbutment DS (K170259)

Reference Device
- TruAbutment DS (K152559)
- Zimmer® Patient Specific Abutment (K143505)
- Biomet 3i Certain® (K130949)
- DIO UF(II) Internal Submerged (K161987, K170608, K173975)
- Megagen AnyRidge® (K140091
- Neoss ProActive® (K083561)

General Description

The TruAbutment DS system includes custom abutments which are placed into the dental implant to provide support for a prosthetic restoration. The subject abutments are indicated for cemented or screw-retained restorations. The custom 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 custom abutments take into consideration the shape of 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 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 proposed abutments are available in internal hex connection, and are compatible with Biomet 3i Certain® Implant/DIO UF(II) Internal Submerged Implant/Megagen AnyRidge® Implant/Neoss ProActive® Implant. The available range of diameters is summarized below:

Implant System	Implant Ø (mm)	Implant Length (mm)	Model Number (mm)	Implant Platform (mm)	Type of Implant-Abutment Connection
Biomet 3i Certain® (K130949)	3.25	8.5	IFNT3285	3.4	Internal Hex
		10	IFNT3210		
		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)N3308	Narrow (K161987)	Internal Hex
		10	UF(II)N3310		
		11.5	UF(II)N3311		
		13	UF(II)N3313		
		15	UF(II)N3315		
	3.8	8.5	UF(II)3808S	Regular (K170608)	
		10	UF(II)3810S		
		11.5	UF(II)3811S		
		13	UF(II)38013		
		15	UF(II)38015		
		16	UF(II)3816S		

Implant System	Implant Ø (mm)	Implant Length (mm)	Model Number (mm)	Implant Platform (mm)	Type of Implant-Abutment Connection
	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		
		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		

Implant System	Implant Ø (mm)	Implant Length (mm)	Model Number (mm)	Implant Platform (mm)	Type of Implant-Abutment Connection
		10	UF(II)7010S		
		11.5	UF(II)7011S		
		13	UF(II)7013S		
Megagen AnyRidge® (K140091)	3.5	8	FANIHX3508	3.1	Internal Hex
		10	FANIHX3510		
		11.5	FANIHX3511		
		13	FANIHX3513		
		15	FANIHX3515		
		18	FANIHX3518		
	4.0	8	FANIHX4008		
		10	FANIHX4010		
		11.5	FANIHX4011		
		13	FANIHX4013		
		15	FANIHX4015		
		18	FANIHX4018		
	4.5	7	FANIHX4508		
		8	FANIHX4508		
		10	FANIHX4510		
		11.5	FANIHX4511		
		13	FANIHX4513		
		15	FANIHX4515		
		18	FANIHX4518		
	5.0	7	FANIHX5007		
		8	FANIHX5008		
		10	FANIHX5010		
		11.5	FANIHX5011		
		13	FANIHX5013		
		15	FANIHX5015		
		18	FANIHX5018		
	5.5	7	FANIHX5507		
		8	FANIHX5508		
		10	FANIHX5510		
		11.5	FANIHX5511		
		13	FANIHX5513		
		15	FANIHX5515		
		18	FANIHX5518		
Neoss ProActive® (K083561)	3.25	9	21176	3.5	Internal Hex
		11	21177		
		13	21178		
		15	21179		

Implant System	Implant Ø (mm)	Implant Length (mm)	Model Number (mm)	Implant Platform (mm)	Type of Implant-Abutment Connection
	3.5	7	21181	4.0	
		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		
	6.5	9	21212		
		11	21213		
		13	21221		
		15	21222		

Indication for Use

The 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:

- Biomet 3i 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** mm
- Megagen AnyRidge® (K140091) **3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0** mm
- Neoss ProActive® (K083561) **3.25, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0** mm

The available range of diameters is summarized below:

Biomet 3i Certain® (K130949)
Implant Ø (mm) : 3.25 / Implant Platform (mm) : 3.4 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 4.0 / Implant Platform (mm) : 4.1 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 5.0 / Implant Platform (mm) : 5.0 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 6.0 / Implant Platform (mm) : 6.0 / Type of Implant-Abutment Connection : Internal Hex

DIO UF(II) Internal Submerged (K161987, K170608, K173975)
Implant Ø (mm) : 3.3 / Implant Platform (mm) : Narrow / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 3.8 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 4.0 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 4.5 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 5.0 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 5.5 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 6.0 / Implant Platform (mm) : Wide / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 6.5 / Implant Platform (mm) : Wide / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 7.0 / Implant Platform (mm) : Wide / Type of Implant-Abutment Connection : Internal Hex

Megagen AnyRidge® (K140091)
Implant Ø (mm) : 3.5 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 4.0 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 4.5 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 5.0 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 5.5 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex

Neoss ProActive® (K083561)
Implant Ø (mm) : 3.25 / Implant Platform (mm) : 3.5 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 3.5 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 4.0 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 4.5 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 5.0 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 5.5 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 6.0 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex

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.

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.

Attributes	Proposed Device	Primary Predicate Device	Equivalence Discussion
Trade Name	TruAbutment DS (K191913)	TruAbutment DS (K170259)	
Indications for Use	The TruAbutment DS is a patient-specific CAD/CAM custom abutment, directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. It is compatible with following systems: • Biomet 3i 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 mm • Megagen AnyRidge® (K140091) 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0 mm • Neoss ProActive® (K083561) 3.25, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 mm The available range of diameters is summarized below: Biomet 3i Certain® (K130949) Implant Ø (mm) : 3.25 / Implant Platform (mm) : 3.4 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 4.0 / Implant Platform (mm) : 4.1 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 5.0 / Implant Platform (mm) : 5.0 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 6.0 / Implant Platform (mm) : 6.0 / Type of Implant-Abutment Connection : Internal Hex DIO UF(II) Internal Submerged (K161987, K170608, K173975) Implant Ø (mm) : 3.3 / Implant Platform (mm) : Narrow / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 3.8 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 4.0 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 4.5 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 5.0 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 5.5 / Implant Platform (mm) : Regular / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 6.0 / Implant Platform (mm) : Wide / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 6.5 / Implant Platform (mm) : Wide / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 7.0 / Implant Platform (mm) : Wide / Type of Implant-Abutment Connection : Internal Hex Megagen AnyRidge® (K140091) Implant Ø (mm) : 3.5 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 4.0 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 4.5 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 5.0 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 5.5 / Implant Platform (mm) : 3.1 / Type of Implant-Abutment Connection : Internal Hex Neoss ProActive® (K083561) Implant Ø (mm) : 3.25 / Implant Platform (mm) : 3.5 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 3.5 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 4.0 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 4.5 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 5.0 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 5.5 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 6.0 / Implant Platform (mm) : 4.0 / Type of Implant-Abutment Connection : Internal Hex 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.	The TruAbutment DS is a patient-specific CAD/CAM custom abutment, directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. It is compatible with all diameters of the Osstem TS Fixture System which consists of Mini (2.08mm) and Regular (2.48mm) interface sizes / Zimmer SV/TSV 3.7, 4.1, 4.7, 6.0 mm interface sizes 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.	**Equivalent** The basic indication of providing support for prostheses is identical. The subject devices are compatible with the same CAD/CAM System as the primary predicate device

Attributes	Proposed Device	Primary Predicate Device	Equivalence Discussion
Trade Name	TruAbutment DS (K191913)	TruAbutment DS (K170259)	
Connection	Internal Hex	Internal Hex	**Equivalent**
Sterility	Packaged Non-sterile	Packaged Non-sterile	**Equivalent**
Material	Ti-6AI-4V ELI	Ti-6AI-4V ELI	**Equivalent**
Abutment	0~25	0~25	**Equivalent**
Dimensions	Biomet 3i 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 mm Megagen AnyRidge® (K140091) 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0 mm Neoss ProActive® (K083561) 3.25, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 mm	Osstem TS Fixture System 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 7.0 mm Zimmer SV/TSV 3.7, 4.1. 4.7, 6.0 mm	**Slightly difference** The Indications for Use of the subject and predicate devices are identical other than the compatible implant bodies.
Abutment Seat	Sits on Taper	Sits on Taper	**Equivalent**
Anatomical	Oral Cavity	Oral Cavity	**Equivalent**
Construction	Machined	Machined	**Equivalent**
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.	**Equivalent**

Substantial Equivalence Discussion

The subject device is substantially equivalent in indications and design principles to the predicate device devices listed above. Provided tables are comparing the Indications for Use and the technological characteristics of the subject device, the primary predicate device.

TruAbutment DS incorporates the same material, indications for use, dimension, design, abutment seat, screw seat, anatomical site, connection, type of retention and technological characteristics as the predicate device. The Indications for Use of the subject and predicate devices are identical other than the compatible implant bodies.

Minor differences in the designs, dimensions, sizes, or compatible OEM implant lines among the subject device, the primary predicate device, and the reference devices do not affect substantial equivalence. These minor differences do not impact substantial equivalence because these differences are related to the compatible OEM implant designs, or are mitigated by the mechanical performance testing.

Mechanical performance testing was performed according to ISO 14801 and FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments". For each 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.

Both the predicate and subject devices are intended to be milled into patient-specific abutments using CAD/CAM technology under the manufacturing control of the sponsor.
Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicate.

Non-clinical Testing

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

- Fatigue Test according to ISO 14801:2007

Below tests were performed for 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.

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 of the worst-case scenario, (smallest diameter with maximum angulation) through fatigue testing.

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 implant body as well as the 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. Clinical testing was not necessary to establish substantial equivalency of the device.

Conclusion

The TruAbutment DS 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 and its predicate are substantially equivalent.