March 03, 2021

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

Re: K201197
Trade/Device Name: TruAbutment DS, TruBase S
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 10, 2021
Received: February 23, 2021

Dear Chris Choi:

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

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

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

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

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

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K201197

Device Name
TruAbutment DS, TruBase S

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:

- Zimmer 3.1mmD Dental Implant System (K142082)
- Screw Vent® and Tapered Screw Vent® (K013227)
- Nobel Active 3.0 (K102436)
- Nobel Active Internal Connection Implant (K071370)

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

TruAbutment DS is compatible with the following devices:

Zimmer 3.1mmD Dental Implant System(K142082)
Implant Body Diameter 3.1/ Implant Platform Diameter 2.9 / Internal Hex

Screw Vent® and Tapered Screw Vent® (K013227)
Implant Body Diameter 3.7/ Implant Platform Diameter 3.5 / Internal Hex
Implant Body Diameter 4.1/ Implant Platform Diameter 3.5 / Internal Hex
Implant Body Diameter 4.7/ Implant Platform Diameter 4.5 / Internal Hex
Implant Body Diameter 6.0/ Implant Platform Diameter 5.7 / Internal Hex

Nobel Active 3.0 (K102436)
Implant Body Diameter 3.0/ Implant Platform Diameter 3.0 / Internal Hex

Nobel Active Internal Connection Implant (K071370)
Implant Body Diameter 3.5/ Implant Platform Diameter NP / Internal Hex
Implant Body Diameter 4.3/ Implant Platform Diameter RP / Internal Hex
Implant Body Diameter 5.0/ Implant Platform Diameter RP / Internal Hex
Implant Body Diameter 5.5/ Implant Platform Diameter WP / Internal Hex

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

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

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K201197

Device Name
TruAbutment DS, TruBase S

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

• Zimmer 3.1mmD Dental Implant System (K142082)
• Screw Vent® and Tapered Screw Vent® (K013227)

TruBase S is intended to be sent to a TruAbutment-validated milling center for manufacture.

TruBase S is compatible with the following devices:

Zimmer 3.1mmD Dental Implant System(K142082)
Implant Body Diameter 3.1/ Implant Platform Diameter 2.9 / Internal Hex

Screw Vent® and Tapered Screw Vent® (K013227)
Implant Body Diameter 3.7/ Implant Platform Diameter 3.5 / Internal Hex
Implant Body Diameter 4.1/ Implant Platform Diameter 3.5 / Internal Hex
Implant Body Diameter 4.7/ Implant Platform Diameter 4.5 / Internal Hex
Implant Body Diameter 6.0/ Implant Platform Diameter 5.7 / Internal Hex

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary
K201197

Submitter
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Device Information

- Trade Name: TruAbutment DS,
  TruBase S
- 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: 03/24/2021

Predicate Devices/ Reference Devices:

Predicate Devices:

TruAbutment DS (K170259) by TruAbutment Inc.

TruBase S (K171532) by TruAbutment Inc.

Reference Devices:

Zimmer 3.1mmD Dental Implant System (K142082) by Zimmer Dental, Inc.

Screw Vent® and Tapered Screw Vent® (K013227) by Sulzer Dental Inc.

Nobel Active 3.0 (K102436) by Nobel Biocare.

Nobel Active Internal Connection Implant (K071370) by Nobel Biocare.

Dess Dental Smart Solution (K170588) by Terrats Medical SL

InCoris Zi (K123664) by Sirona Dental Systems GmbH.

3shape Abutment Designer Software (K151455) by 3Shape A/S.

RelyX Unicem 2Automix (K100756) by 3M ESPE

TruAbutment DS (K172304) by TruAbutment Inc.

TruAbutment DS (K152559) by TruAbutment Inc.

URIS OMNI Narrow System & Prosthetic (K200817) by TruAbutment Inc.

General Description

TruAbutment DS

TruAbutment DS system includes patient-specific abutments that are placed into the dental implant to provide support for prosthetic restoration. The subject abutments are indicated for cemented or screw-retained restorations. The patient-specific abutment screws 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 the 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 proposed abutments are available in internal hex connection, and are compatible with the following systems:

- Zimmer 3.1mmD Dental Implant System (K142082)
- Screw Vent® and Tapered Screw Vent® (K013227)
- Nobel Active 3.0(K102436)
- Nobel Active Internal Connection Implant (K071370)

Design Limitation for TruAbutment DS

Design parameter	Design Limit
Minimum and Maximum abutment angle	0~25°
Minimum and Maximum Cuff Height	0.5~ 6.0mm
Minimum and Maximum diameter at abutment/implant interface	∅3.5mm~∅8.0mm
Minimum Thickness	0.4 mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4 ~7 mm

TruBase S

TruBase S consists of a two-piece abutment, where the titanium base is a pre-manufactured abutment that will be used to support a CAD/CAM designed superstructure (the second part of the two-piece abutment) that composes the final abutment.

TruBase S abutments are made of titanium alloy conforming to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications and are provided in various prosthetic platform diameters (Zimmer 3.1mmD Dental Implant System: 2.9mm and Screw Vent® and Tapered Screw Vent®: 3.5, 4.5, 5.7mm).
They also feature:

- cylindrical shape
- hexagonal indexing at the apical end of the connection
- indexing guide in the cementable portion for coping fitting

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 S in the lab. Use "RelyX Unicem 2Automix" as an adhesive extra orally to connect.

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

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 S Engaging**	**TruBase S Non-Engaging**
Zimmer 3.1mmD				
2.9	O	O	O	O
Screw Vent® and Tapered Screw Vent®				
3.5	X	O	O	O
4.5	X	O	O	O
5.7	X	O	O	O
NobelActive 3.0				
3.0	O	O	X	X
Nobel Active Internal				
NP	X	O	X	X
RP	X	O	X	X
WP	X	O	X	X

X: Not included in this submission

O: Included in this submission

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	∅5.0mm~∅8.0mm
Minimum Thickness	0.4 mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4 ~6 mm

Indication for Use

TruAbutment DS

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

- Zimmer 3.1mmD Dental Implant System (K142082)
- Screw Vent® and Tapered Screw Vent® (K013227)
- Nobel Active 3.0 (K102436)
- Nobel Active Internal Connection Implant (K071370)

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

TruAbutment DS is compatible with the following devices:

Zimmer 3.1mmD Dental Implant System(K142082)
Implant Body Diameter 3.1/ Implant Platform Diameter 2.9 / Internal Hex

Screw Vent® and Tapered Screw Vent® (K013227)
Implant Body Diameter 3.7/ Implant Platform Diameter 3.5 / Internal Hex
Implant Body Diameter 4.1/ Implant Platform Diameter 3.5 / Internal Hex
Implant Body Diameter 4.7/ Implant Platform Diameter 4.5 / Internal Hex
Implant Body Diameter 6.0/ Implant Platform Diameter 5.7 / Internal Hex
Nobel Active 3.0 (K102436)

Implant Body Diameter 3.0/ Implant Platform Diameter 3.0 / Internal Hex

Nobel Active Internal Connection Implant (K071370)
Implant Body Diameter 3.5/ Implant Platform Diameter NP / Internal Hex
Implant Body Diameter 4.3/ Implant Platform Diameter RP / Internal Hex
Implant Body Diameter 5.0/ Implant Platform Diameter RP / Internal Hex
Implant Body Diameter 5.5/ Implant Platform Diameter WP / Internal Hex

TruBase S

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

- Zimmer 3.1mmD Dental Implant System (K142082)
- Screw Vent® and Tapered Screw Vent® (K013227)

TruBase S is intended to be sent to a TruAbutment-validated milling center for manufacture.

TruBase S is compatible with the following devices:

Zimmer 3.1mmD Dental Implant System(K142082)
Implant Body Diameter 3.1/ Implant Platform Diameter 2.9 / Internal Hex

Screw Vent® and Tapered Screw Vent® (K013227)
Implant Body Diameter 3.7/ Implant Platform Diameter 3.5 / Internal Hex
Implant Body Diameter 4.1/ Implant Platform Diameter 3.5 / Internal Hex
Implant Body Diameter 4.7/ Implant Platform Diameter 4.5 / Internal Hex
Implant Body Diameter 6.0/ Implant Platform Diameter 5.7 / Internal Hex

TruAbutment DS and TruBase S 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
Zimmer 3.1mmD Dental Implant System (K142082)	3.1	8mm	CM318	2.9	Internal Hex
		10mm	CM3110		
		11.5mm	CM3111		
		13mm	CM3113		
		16mm	CM3116		
Screw Vent® and Tapered Screw Vent® (K013227)	3.7	8mm	TSVTB8	3.5	Internal Hex
		10mm	TSVTB10		
		11.5mm	TSVTB11		
		13mm	TSVTB13		
		16mm	TSVTB16		
	4.1	8mm	TSVT4B8	3.5	
		10mm	TSVT4B10		
		11.5mm	TSVT4B11		
		13mm	TSVT4B13		
		16mm	TSVT4B16		
	4.7	8mm	TSVTWB8	4.5	
		10mm	TSVTWB10		
		11.5mm	TSVTWB11		
		13mm	TSVTWB13		
		16mm	TSVTWB16		
	6.0	8mm	TSVT6B8	5.7	
		10mm	TSVT6B10		
		11.5mm	TSVT6B11		
		13mm	TSVT6B13		
		16mm	TSVT6B16		
Nobel Active 3.0 (K102436)	3.0	10mm	36769	3.0	Internal Hex
		11.5mm	36770		
		13mm	36771		
		15mm	36772		
Nobel Active Internal Connection Implant (K071370)	3.5	8.5mm	35221	NP	Internal Hex
		10mm	34125		
		11.5mm	34126		
		13mm	34127		
		15mm	34128		
		18mm	35215		
	4.3	8.5mm	35223	RP	

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
		10mm	34131		
		11.5mm	34132		
		13mm	34133		
		15mm	34134		
		18mm	35219		
	5.0	8.5mm	35225	RP	
		10mm	34137		
		11.5mm	34138		
		13mm	34139		
		15mm	34140		
		18mm	35220		
	5.5	7mm	37806	WP	
		8.5mm	37807		
		10mm	37808		
		11.5mm	37809		
		13mm	37810		
		15mm	37811		

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	Predicate Device	Reference Device	Equivalence Discussion
Trade Name	TruAbutment DS (K201197)	TruAbutment DS (K170259)	Zimmer 3.1mmD Dental Implant System (K142082)	
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: Zimmer 3.1mmD Dental Implant System (K142082) Screw Vent® and Tapered Screw Vent® (K013227) Nobel Active 3.0 (K102436) Nobel Active Internal Connection Implant (K071370) All digitally designed abutments and/or coping for use with the TruAbutment DS abutments are intended	TruAbutment DS is a patient-specific CAD/CAM abutment, directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. It is compatible with the following systems: Zimmer SV/TSV 3.7, 4.1, 4.7, 6.0 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.	(Implant, Temporary Abutment, Ball Abutment, Healing Collar and Healing Collar Screw Sections of IFUS not applicable to this submission) The 2.9mm Angled Abutment and the 2.9mm Angled Abutment, Straight Hex and are used for attachment of restorations requiring off-axis correction. The 2.9mm Angled Abutment and the 2.9mm Angled Abutment, Straight Hex are designed to be used in edentulous or partially edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement. The 2.9mm	**Equivalent** Similar to a predicate device and reference device, both are indicated for single or multiple prosthesis of partially or completely edentulous jaws. Both are intended for surgical placement in the upper or lower jaw. The subject devices are compatible with the same CAD/CAM System as the predicate device.

	to be sent to a TruAbutment-validated milling center for manufacture. TruAbutment DS is compatible with the following devices: Zimmer 3.1mmD Dental Implant System(K142082) Implant Body Diameter 3.1/ Implant Platform Diameter 2.9 / Internal Hex Screw Vent® and Tapered Screw Vent® (K013227) Implant Body Diameter 3.7/ Implant Platform Diameter 3.5 / Internal Hex Implant Body Diameter 4.1/ Implant Platform Diameter 3.5 / Internal Hex Implant Body Diameter 4.7/ Implant Platform Diameter 4.5 / Internal Hex Implant Body Diameter 6.0/ Implant Platform Diameter 5.7 / Internal Hex Nobel Active 3.0 (K102436) Implant Body Diameter 3.0/ Implant Platform		Contour Abutment and the 2.9mm Contour Abutment, Straight Hex are used as a terminal or intermediate abutment for a cemented prosthesis. Abutment can be used for a single- or multiple-unit restoration. The 2.9mm Angled Contour Abutment and the 2.9mm Angled Contour Abutment, Straight Hex are designed to be used as a terminal or intermediate abutment for a cemented prosthesis where the angle needs to be offset by 17°. Abutment can be used for a single- or multiple-unit restoration.	

	Diameter 3.0 / Internal Hex Nobel Active Internal Connection Implant (K071370) Implant Body Diameter 3.5/ Implant Platform Diameter NP / Internal Hex Implant Body Diameter 4.3/ Implant Platform Diameter RP / Internal Hex Implant Body Diameter 5.0/ Implant Platform Diameter RP / Internal Hex Implant Body Diameter 5.5/ Implant Platform Diameter WP / Internal Hex			
Connection	Internal Hex	Internal Hex	Internal Hex	same
Sterility	Packaged Non-sterile	Packaged Non-sterile	Packaged Non-sterile	same
Material	Ti-6AI-4V ELI	Ti-6AI-4V ELI	Titanium 6Al-4V ELI	same
Abutment Angle ˚	0~25 ˚	0~25 ˚	20 ˚	Similar, the angulation (0~25˚) is broader than the reference device.
Abutment Seat	Sits on Taper	Sits on Taper	Sits on Taper	same
Anatomical	Oral Cavity	Oral Cavity	Oral Cavity	same
Construction	Machined	Machined	Machined	same
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.	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.	same

TruBase S

Attributes	Proposed Device	Predicate Device	Reference Device	Equivalence Discussion
Trade Name	TruBase S (K201197)	TruBase S (K171532)	Dess Dental Smart Solution (K170588)	
Indications for Use	TruBase S is a titanium component that is directly connected to endosseous dental implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible with the following systems: Zimmer 3.1mmD Dental Implant System (K142082) Screw Vent® and Tapered Screw Vent® (K013227) TruBase S is intended to be sent to a	TruBase S is a titanium component that is directly connected to endosseous dental implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible with the following systems: Zimmer TSV - 3.7, 4.1, 4.7, 6.0 mm All digitally designed abutments and/or coping for use with the TruBase S are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MCX or MC XL milling unit.	Dess Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with TiBase or Pre-milled Blank are to be sent to Terrats Medical validated milling center for manufacture. **Compatible Implant System** 3i Certain 3.25,4.0,5.0 (3.4,4.1,5.0 Platform Diameter) 3i OSSEOTITE 3.25,3.75,4.0,5.0 (3.4,4.1,5.0) Osseo Speed 3.5,4.0,5.0 (3.5/4.0, 4.5/5.0) FRIADENT Xive 3.4,3.8,4.5 (3.4, 3.8, 4.5) Nobel Active 3.5,4.3,5.0	**Equivalent** Similar to a predicate device and reference device, both are indicated for single or multiple prosthesis of partially or completely edentulous jaws. Both are intended for surgical placement in the upper or lower jaw. The subject devices are compatible with the same CAD/CAM System as the predicate device.

	TruAbutment-validated milling center for manufacture. TruBase S is compatible with the following devices: Zimmer 3.1mmD Dental Implant System(K142082) Implant Body Diameter 3.1/ Implant Platform Diameter 2.9 / Internal Hex Screw Vent® and Tapered Screw Vent® (K013227) Implant Body Diameter 3.7/ Implant Platform Diameter 3.5 / Internal Hex Implant Body Diameter 4.1/ Implant Platform Diameter 3.5 / Internal Hex Implant Body Diameter 4.7/ Implant		(NP,RP) Nobel Replace Conical 3.5,4.3,5 (NP,RP) Nobel Replace Trilobe 3.5,4.3,5.0 (NP,RP,WP) BraneMark 3.5,3.75/4.0,5.0(NP,RP,WP) Straumnann Bone Level 3.3,4.1,4.8 (NC,RC) Straumann Tissue Level 3.3,4.1,4.8 (RN,WN) Zimmer Tapered Screw Vent 3.7,4.1,4.7,6.0 (3.5,4.5,5.7)	

	Platform Diameter 4.5 / Internal Hex Implant Body Diameter 6.0/ Implant Platform Diameter 5.7 / Internal Hex			
Abutment Diameter(s)	Engaging: 3.5, 3.8, 4.5, 5.7mm Non-Engaging: 3.5, 4.3, 4.5, 5.3, 5.7, 6.5mm	Engaging: 4.3, 5.3, 6.5mm	3.4~6.5mm	Similar, Angulation is within the range of the reference device.
Abutment Height(s)	4.7mm	4.7mm	Not stated in 510(k) summary	same
Material of Abutment	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V alloy	same
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.	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.	same
Type of Retention	Screw-retained.	Screw-retained	Screw-retained	same
Restorative Range of Angulation	Up to 15°	Up to 20°	Straight (0°)	Similar, Angulation is within the range of the predicate device.
Material of Superstructure	InCoris Zi (K123664)	InCoris ZI (K123664)	Not stated in 510(k) summary	same
Patient-Specific Design	CAD/CAM manufactured superstructures	CAD/CAM manufactured superstructures	CAD/CAM manufactured superstructures	same
End-User Sterilization	Moist steam sterilization	Moist steam sterilization	Moist steam sterilization	same

Substantial Equivalence Discussion

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

The Indications for Use Statement (IFUS) for subject device (TruAbutment DS) is substantially equivalent in intended use to the predicate device (K170259), and the reference devices (K142082). 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.

The minor differences between the IFUS for the subject device (TruAbutment DS) and the predicate(K170259) include:

Although the predicate device (K170259) is compatible with Screw Vent® and Tapered Screw Vent® K013227, the subject device (TruAbutment DS) is compatible with, not only Screw Vent® and Tapered Screw Vent® K013227 but also Zimmer 3.1mmD Dental Implant System K142082, Nobel Active 3.0 K102436 and Nobel Active Internal Connection Implant K071370.

The difference between the two products in the design parameters are the same except for the minimum diameter. The minimum diameter of the product compatible with the subject device Zimmer 3.1mmD Dental Implant System K142082 is smaller than K170259.

Design parameter	Subject Device Design Limit	Predicate Device (K170259) Design Limit
Minimum and Maximum abutment angle	0~25°	0~25°
Minimum and Maximum Cuff Height	0.5~ 6.0mm	0.5~ 6.0mm
Minimum and Maximum diameter at abutment/implant interface	∅3.5mm~∅8.0mm	∅4.0mm~∅8.0mm
Minimum Thickness	0.4 mm	0.4 mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4 ~7 mm	4 ~7 mm

This submission includes Screw Vent® and Tapered Screw Vent® K013227, Nobel Active 3.0 K102436 and Nobel Active Internal Connection Implant K071370 compatible Non-Engaging products. These products are all identical except for the connection type in the previously cleared K170259 and K172304.

TruAbutment DS compatible with Screw Vent® and Tapered Screw Vent®	
Engaging	Non-Engaging
K170259	Subject device
has cleared with K170259 (in prior 510k submission) No other Modification (e.g. Coating Change, Manufacturing Process, Material, etc)	

TruAbutment DS compatible with Nobel Active Internal Connection Implant	
Engaging	Non-Engaging
K172304	Subject device
has cleared with K172304 (in prior 510k submission) No other Modification (e.g. Coating Change, Manufacturing Process, Material, etc)	

(K172304: TruAbutment DS compatible with Astra Tech OsseoSpeed™ EV, Nobel Active™ Internal Connection Implant, Straumann® Bone Level Implants)

The Indications for Use Statement (IFUS) for subject device (TruBase S) is substantially equivalent in intended use to the predicate device (K171532), and the reference devices (K170588). 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. The subject device and the predicate device have same material (Ti-6Al-4V ELI), compatible OEM Implant line, validated milling center.

The minor differences between the IFUS for the subject device and the predicate device is angulation and software.
The difference between the two products in the design parameters are the same except for the minimum diameter. The minimum diameter of the product compatible with the subject device Zimmer 3.1mmD Dental Implant System K142082 is smaller than K171532. The angle of predicate device K171532 is 20°, while the subject device (TruBase S) can be designed up to 15°

Design parameter	Subject Device Design Limit	Predicate Device (K171532) Design Limit
Minimum and Maximum abutment angle	0~15°	0~20°
Minimum and Maximum Cuff Height	0.5~5 mm	0.5~5 mm

Design parameter	Subject Device Design Limit	Predicate Device (K171532) Design Limit
Minimum and Maximum diameter at abutment/implant interface	∅5.0mm~∅8.0mm	∅6.0mm~∅8.0mm
Minimum Thickness	0.4 mm	0.4 mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4 ~6 mm	4 ~6 mm

This submission includes Screw Vent® and Tapered Screw Vent® K013227 compatible Non-Engaging products. These products are all identical except for the connection type in the previously cleared K171532.

TruBase S compatible with Tapered Screw Vent®	
Engaging	Non-Engaging
K171532	Subject device
has cleared with K171532 (in prior 510k submission) No other Modification (e.g. Coating Change, Manufacturing Process, Material, etc)	

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 is leveraged from previous 510k (K152559):

- End User Steam Sterilization Test according to ISO 17665-1:2006, 17665-2:2009 and ANSI/AAMI ST79:2010.
- Biocompatibility testing for cytotoxicity, Intracutaneous Reactivity and Sensitization according to ISO 10993-5:2009 “Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity”, ISO 10993-10:2010 “Part 10: Tests for irritation and skin sensitization” and ISO 10993-10:2010 “Chapter 9 Murine Local Lymph Node Assay”.

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.

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, (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 abutment and implant body. 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, TruBase S 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 S and its predicate are substantially equivalent.