



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
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May 25, 2017

TruAbutment Inc.
c/o April Lee
Consultant
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Rowland Heights, California 91748

Re: K170259
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: April 21, 2017
Received: April 27, 2017

Dear April Lee:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

 Tina Kiang
-S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K170259

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:

- 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.

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: 04/21/2017

General Description

The TruAbutment DS system includes patient-specific abutments which are placed into the dental implant to provide support for a prosthetic restoration. The subject abutments are indicated for cemented or “Screw- and Cement-Retained Prosthesis” (SCRCP) restorations. The patient-specific abutment and abutment screw are made of Titanium grade Ti-6Al-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 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 patient-specific abutments are available in internal connection, and are compatible with Zimmer Screw Vent and Tapered Screw Vent. The available range of diameters is summarized below:

Implant System	Implant Ø (mm)	Implant Platform (mm)	Type of Implant-Abutment Connection
Zimmer Screw Vent / Tapered Screw Vent	3.7	3.5	Internal Hex
	4.1		
	4.7	4.5	
	6	5.7	

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:

- 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.

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.

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 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.

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 OEM implant body as well as the OEM implant 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.

Predicate Devices:

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

- Primary Predicate
 - TruAbutment DS (K152559)
- Reference Predicate
 - Zimmer® Patient Specific Abutment Internal Hex (K143505)

Comparison between Predicate and Proposed Device

Attributes	Proposed Device	Predicate Device	Reference Device
Trade Name	TruAbutment DS	TruAbutment DS (K152559)	Zimmer® Patient Specific Abutment, Internal Hex (K143505)
Indications 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: • 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.	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. 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 Zimmer® Patient Specific Abutment is used as a terminal or intermediate abutment for a cemented prosthesis. The abutment can be used for a single or multiple-unit restoration.
Connection	Internal Hex	Internal Hex	Internal Hex
Sterility	Packaged Non-sterile	Packaged Non-sterile	Packaged Non-sterile
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V
Abutment Angle °	0~25	0~25	0~30

Dimensions	Zimmer SV/TSV 3.7, 4.1, 4.7, 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
Abutment Seat	Sits on Taper	Sits on Taper	Sits on Taper
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity
Construction	Machined	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.	Screw-retained to the implant. The prosthesis can be cement-retained to the

Substantial Equivalence Discussion

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. This difference is mitigated by fatigue testing, reverse engineering, dimensional analysis, and identification of reference predicate for compatible implant bodies. 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 and do not raise different questions of safety and effectiveness than the predicate.

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.