DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 20, 2016

TruAbutment, Inc.
% Ms. April Lee
Consultant
WithUS Group Inc
2531 Pepperdale Drive
Rowland Heights, California 91748

Re: K152559
Trade/Device Name: TruAbutment DS
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: April 15, 2016
Received: April 20, 2016

Dear Ms. 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 yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152559

Device Name
TruAbutment DS

Indications for Use *(Describe)*
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.

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
TruAbutment Inc.
Brandon Kim
300 S. Harbord Blvd #520
Anaheim, CA 92805
USA
Email: Brandon.kim@truabutment.com
Phone: 1-714-956-1488

Official Correspondent
WithUS Group Inc
April Lee
2531 Pepperdale Drive,
Rowland Heights, CA 9174
USA
Email: withus6664@gmail.com
Phone: 1-909-274-9971
Fax: 1-909-460-8122

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: 5/18/2016

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-I 36) for Osstem TS Fixture System (K121995) which consists of both Mini and Regular interface sizes. Each custom 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 custom abutments are available in internal hex connection, and are compatible with the Osstem TS Fixture System implant bodies. The Osstem TS Fixture System consists of two interface hex

sizes which are 2.08mm (Mini) and 2.48mm (Regular). The available range of diameters is summarized below:

Implant System	Implant Diameter (mm)	Platform Connection Size (mm)	Type of Implant-Abutment Connection
Osstem TS Fixture System	3.5	2.08 (Mini)	Internal Hex
	4.0	2.48 (Regular)	Internal Hex
	4.5		Internal Hex
	5.0		Internal Hex
Osstem TS Fixture System (Ultra Wide)	6.0		Internal Hex
	7.0		Internal Hex

Indication 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 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.

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

- 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.
- Fatigue Test according to ISO 14801:2007

Non-clinical test data was used to evaluate the proposed device's substantial equivalence compared to the predicate device. The result 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.

Predicate Devices:

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

- ET SmartFit Abutment K123627

Comparison between Predicate and Proposed Device

Attributes	Proposed Device	Predicate Device
	TruAbutment DS	ET SmartFit Abutment (K123627)
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 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.	ET SmartFit Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Dimensions	Interface Hex Size: Mini (2.08 mm) and Regular (2.48 mm)	Interface Hex Size: Mini (2.08 mm) and Regular (2.48 mm)
Connection	Internal Hex	Internal Hex
Sterility	Packaged Non-sterile	Packaged Non-sterile
Material	Ti-6AI-4V ELI	Ti-6AI-4V ELI
Picture of Abutment	(Milled from rods) Mini	(Milled from puck) Mini

	 Regular 	 Regular 
Picture of Screw	Mini  Regular 	Mini  Regular 
Abutment Angle ˚	0~25	0~30
Abutment Seat	Sits on Taper	Sits on Taper
Screw 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.

Substantial Equivalence Discussion

TruAbutment DS incorporates the same material, similar 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 feature different language or wording. However, both the subject and predicate device share the same intended use, namely to serve as an aid in prosthetic reconstructions, such as crowns, bridges or overdentures. Also 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.

The only other difference between the subject device and primary predicate is the manufacturing process and the maximum angulation of the abutment design. While the industry standard for CAD/CAM abutment is usually 30º, TruAbutment placed limitation on the abutment design at 25ºin order to limit instances of having to re-design extraordinarily long abutments where the head protrudes from of the 14 mm Ø titanium rods. Other than this difference, there aren't any further variations between the two devices which would anyway impede the substantially equivalent decision.

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.