January 29, 2020

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

Re: K183106
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: January 3, 2020
Received: January 3, 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)*
K183106

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:

- Tapered Internal Implants (K071638) (K143022) 3.4, 3.8, 4.6, 5.8 mm
- BioHorizons Laser-Lok Implant System (K093321) 3.0 mm

The available range of diameters is summarized below:

Tapered Internal / Laser-Lok 3.0
Implant Ø (mm) : 3.0 / Implant Platform (mm) : 3.0 / Type of Implant-Abutment Connection : Internal Hex
Tapered Internal
Implant Ø (mm) : 3.4 / Implant Platform (mm) : 3.0 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 3.8 / Implant Platform (mm) : 3.5 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 4.6 / Implant Platform (mm) : 4.5 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 5.8 / Implant Platform (mm) : 5.7 / 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.

510(k) Summary

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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: 01/29/2020

Predicate Devices/Reference Devices

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

Primary Predicate

- TruAbutment DS (K172304)

Reference Devices

- TruAbutment DS (K152559)
- BioHorizons Tapered Internal Implant System (K071638)
- BioHorizons Tapered Internal Implants (K143022)
- BioHorizons Laser-Lok 3.0 Implant System (K093321)

Device 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" (SCRP) restorations. The patient-specific 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 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 connections and are compatible with:

- Tapered Internal Implants (K071638) (K143022)
- BioHorizons Laser-Lok Implant System (K093321)

Implant System	Implant Ø (mm)	Implant Platform (mm)	Type of Implant-Abutment Connection
Tapered Internal / Laser-Lok 3.0	3.0	3.0	Internal Hex
Tapered Internal	3.4	3.0	
	3.8	3.5	
	4.6	4.5	
	5.8	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:

- Tapered Internal Implants (K071638) (K143022) 3.4, 3.8, 4.6, 5.8 mm
- BioHorizons Laser-Lok Implant System (K093321) 3.0 mm

The available range of diameters is summarized below:

Tapered Internal / Laser-Lok 3.0
Implant Ø (mm) : 3.0 / Implant Platform (mm) : 3.0 / Type of Implant-Abutment Connection : Internal Hex
Tapered Internal
Implant Ø (mm) : 3.4 / Implant Platform (mm) : 3.0 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 3.8 / Implant Platform (mm) : 3.5 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 4.6 / Implant Platform (mm) : 4.5 / Type of Implant-Abutment Connection : Internal Hex
Implant Ø (mm) : 5.8 / Implant Platform (mm) : 5.7 / 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	Subject Device	Primary Predicate Device	Equivalence Discussion
Trade Name	TruAbutment DS (K183106)	TruAbutment DS (K172304)	
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: • Tapered Internal Implants (K071638) (K143022) 3.4, 3.8, 4.6, 5.8 mm • BioHorizons Laser-Lok Implant System (K093321) 3.0 mm The available range of diameters is summarized below: **Tapered Internal / Laser-Lok 3.0** Implant Ø (mm) : 3.0 / Implant Platform (mm) : 3.0 / Type of Implant-Abutment Connection : Internal Hex **Tapered Internal** Implant Ø (mm) : 3.4 / Implant Platform (mm) : 3.0 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 3.8 / Implant Platform (mm) : 3.5 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 4.6 / Implant Platform (mm) : 4.5 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 5.8 / Implant Platform (mm) : 5.7 / 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 patient-specific 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 Tech OsseoSpeed™ EV 3.0. 3.6, 4.2, 4.8, 5.4 mm • Nobel Active™ 3.5, 4.3, 5.0, 5.5 mm • Straumann® Bone Level 3.3, 4.1, 4.8 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.	**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	Subject Device	Primary Predicate Device	Equivalence Discussion
Trade Name	TruAbutment DS (K183106)	TruAbutment DS (K172304)	
Connection	Internal Connections	Internal Connections	**Equivalent**
Sterility	Packaged Non-sterile	Packaged Non-sterile	**Equivalent**
Material	Ti-6AI-4V ELI	Ti-6AI-4V ELI	**Equivalent**
Abutment Angle ˚	0~25	0~25	**Equivalent**
Dimensions	• Tapered Internal Implants (K071638) (K143022) 3.4, 3.8, 4.6, 5.8 mm • BioHorizons Laser-Lok Implant System (K093321) 3.0 mm	• Astra Tech OsseoSpeed™ EV 3.0. 3.6, 4.2, 4.8, 5.4 mm • Nobel Active™ 3.5, 4.3, 5.0, 5.5 mm • Straumann® Bone Level 3.3, 4.1, 4.8 mm	**Equivalent**
Abutment Seat	Sits on Taper	Sits on Taper	**Equivalent**
Anatomical Site	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**
Principle Operation	The proposed device is manufactured components utilized for digital prosthetic solutions as an aid in prosthetic restoration. The abutments are fixed to the underlying implant with an abutment screw, upon which a CAD/CAM designed restoration may be processed to complete a dental prosthesis.	The proposed device is manufactured components utilized for digital prosthetic solutions as an aid in prosthetic restoration. The abutments are fixed to the underlying implant with an abutment screw, upon which a CAD/CAM designed restoration may be processed to complete a dental prosthesis.	**Equivalent**

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.

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 were performed for reference 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 compatible implant body as well as the OEM implant body, the OEM implant abutment, and the OEM abutment 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.