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

January 23, 2018

Re: K172304
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: December 21, 2017
Received: December 28, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For
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

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)*
K172304

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:
- Astra Tech OsseoSpeed™ EV 3.0, 3.6, 4.2, 4.8, 5.4 mm
- Nobel Active™ Internal Connection Implant 3.5, 4.3, 5.0, 5.5 mm
- Straumann® Bone Level Implants 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.

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.

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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: 1/18/2018

**Predicate Devices**

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

- Primary Predicate
  - TruAbutment DS (K170259)

- Reference Predicate
  - Astra Tech OsseoSpeed™ EV (K121810)
  - NobelProcera Ti Abutment (K091756)
  - Straumann® CARES® Titanium Abutment (K052272, K072151, K081005, K082764)

**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-I 36). 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.

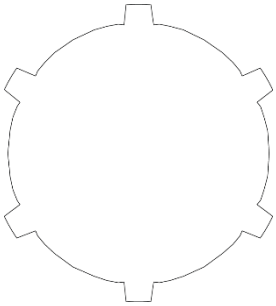
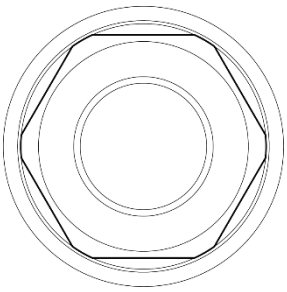
The abutment is placed over the implant shoulder and mounted into the implant with the provided screw. All manufacturing processes of TruAbutment DS are conducted at the TruAbutment milling center and provided to the authorized end-user as a final patient-specific abutment.

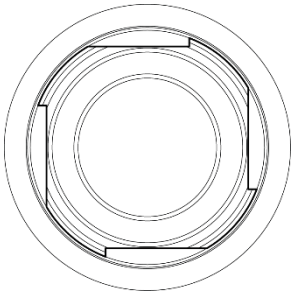
Mechanical resistance of the implant-abutment connection is essential to ensure correct long-term functional performance of the complete dental restoration. Dimensional compatibility and mechanical performance of bases and screws together with the underlying implant are of primary importance. These concepts 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:

- Astra Tech OsseoSpeed™ EV (K120414, K130999)
- Nobel Active™ Internal Connection Implant (K071370)
- Straumann® Bone Level Implants (K062129, K140878, K153758, K150938)

The available range of diameters is summarized below:

<table>
<tr><th>Implant System</th><th>Implant Ø (mm)</th><th>Interface Connection Type/Size (mm)</th><th>Implant-Abutment Connection and Anti-Rotational Feature</th></tr>
<tr><td rowspan="5">Astra Tech OsseoSpeed™ EV</td><td>3.0</td><td>3.0</td><td rowspan="5">Internal Spline “Index System”<br>  </td></tr>
<tr><td>3.6</td><td>3.6</td></tr>
<tr><td>4.2</td><td>4.2</td></tr>
<tr><td>4.8</td><td>4.8</td></tr>
<tr><td>5.4</td><td>5.4</td></tr>
<tr><td rowspan="4">Nobel Active™ Internal Connection Implant</td><td>3.5</td><td>NP</td><td rowspan="4">Internal Hex<br>  </td></tr>
<tr><td>4.3</td><td rowspan="2">RP</td></tr>
<tr><td>5.0</td></tr>
<tr><td>5.5</td><td>WP</td></tr>
</table>

| | | | |
|---|---|---|---|
| Straumann® Bone Level Implants | 3.3 | NC | Internal Cross Fit®  |
| | 4.1 | RC | |
| | 4.8 | RC | |

**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:

- Astra Tech OsseoSpeed™ EV **3.0, 3.6, 4.2, 4.8, 5.4** mm
- Nobel Active™ Internal Connection Implant **3.5, 4.3, 5.0, 5.5** mm
- Straumann® Bone Level Implants **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.

**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 |
|---|---|---|
| Trade Name | TruAbutment DS | TruAbutment DS (K170259) |
| 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.<br><br>It is compatible with the following systems:<br>• Astra Tech OsseoSpeed™ EV **3.0, 3.6, 4.2, 4.8, 5.4** mm<br>• Nobel Active™ Internal Connection Implant **3.5, 4.3, 5.0, 5.5** mm<br>• Straumann® Bone Level Implants **3.3, 4.1, 4.8** mm<br><br>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 abutment, directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation.<br><br>It is compatible with the following systems:<br>• Zimmer SV/TSV **3.7, 4.1, 4.7, 6.0** mm<br><br>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. |
| Connection | Internal Connections | Internal Hex |
| Sterility | Packaged Non-sterile | Packaged Non-sterile |
| Material | Ti-6AI-4V ELI | Ti-6AI-4V ELI |
| Abutment Angle ˚ | 0~25 | 0~25 |
| Dimensions | Astra Tech OsseoSpeed™ EV 3**.0. 3.6, 4.2, 4.8, 5.4** mm<br>Nobel Active™ **3.5, 4.3, 5.0, 5.5** mm<br>Straumann® Bone Level **3.3, 4.1, 4.8** mm | Zimmer SV/TSV **3.7, 4.1, 4.7, 6.0** mm |
| Abutment 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. |
| 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. |

| Attributes | Reference Device #1 | Reference Device #2 | Reference Device #3 | EQUIVALENCE DISCUSSION |
|---|---|---|---|---|
| Trade Name | Astra Tech OsseoSpeed™ EV (K121810) | NobelProcera Ti Abutment (K091756) | Straumann® CARES® Titanium Abutment (K052272, K072151, K081005, | |
| Indications for Use | OsseoSpeed™ Angled Abutment EV is intended to be used in conjunction with Astra Tech Implant System EV in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for bridges or overdentures. The Atlantis™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant. | The NobelProcera Ti Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. | Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns or bridges. The NC CARES Titanium Abutment is indicated for cemented restoration. The abutment can be used in single tooth replacements and multiple tooth restorations. | **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. |
| Connection | Internal Spline | Internal Hex | Internal Cross Fit® | **Equivalent** |
| Sterility | Packaged Non-sterile | Packaged Non-sterile | Packaged Non-sterile | **Equivalent** |
| Material | Ti-6AI-4V ELI | Ti-6AI-4V ELI or Titanium | Commercially pure | **Equivalent** |
| Abutment | 20 and 30 | UNK | 0~30 | **Equivalent** |
| Dimensions | 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** The dimensions vary by implant system but the subject device and the primary predicate are manufactured from the same company which followed the identical procedure of reverse-engineering the reference predicates that represents each of the three systems subject device is claiming compatibility with. |

| | | | | |
|---|---|---|---|---|
| Abutment | Sits on Taper | Sits on Taper | Sits on Taper | **Equivalent** |
| Anatomical | Oral Cavity | Oral Cavity | Oral Cavity | **Equivalent** |
| Construction | Machined | 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 | Screw-retained to the implant. The prosthesis can be cement-retained | **Equivalent** Identical. |

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 14801:2007

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.

Biocompatibility and sterilization validation test data was used to evaluate the proposed device's substantial equivalence compared to the predicate device which is owned by the applicant. 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 (OEM implant bodies, OEM abutments, OEM fixation screws) 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 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.