September 11, 2018

TruAbutment Inc.
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

Re: K171532
Trade/Device Name: TruBase S
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 4, 2018
Received: September 10, 2018

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,

Andrew I. Steen -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)*
K171532

Device Name
TruBase S

Indications for Use *(Describe)*
The TruBase S is a titanium component that is directly connected to endosseous dental implants to provide support for patient-specific 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 (3.5, 4.5, 5.7mm platform sizes)

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.

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."

510(k) Summary

Submitter
TruAbutment Inc.
Brandon Kim
17742 Cowan,
Irvine, CA 92614
USA
Email: Brandon.kim@truabutment.com
Phone: 1-714-956-1488

Official Correspondent
Withus Group Inc.
April Lee
106 Superior,
Irvine, CA 92620
USA
Email: withus6664@gmail.com
Phone: 1-909-274-9971
Fax: 1-909-460-8122

Device Information

- Trade Name: 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: 09/04/2018

Predicate Devices

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

- Primary Predicate
  - Straumann® Variobase® for CEREC® (K151324)
- Reference Predicate
  - Neodent Implant System Titanium Base for CEREC® (K160964)
  - Link Abutment for CEREC® (K160519)

Device Description

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 (4.3, 5.3, 6.5 mm) and four gingival heights (0.8, 1.8, 2.8, 3.8mm), all having a 4.7mm prosthetic post height. They also feature:

- cylindrical shape
- hexagonal indexing at the apical end of the connection

- indexing guide in the cementable portion for coping fitting

The CAD/CAM patient-specific superstructure that composes the final abutment must be designed and milled through the Sirona Dental CAD/CAM System, according to the prosthetic planning and patient clinical situation.

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

TruBase S is compatible with the following devices:

Dental Implant

- Zimmer TSV - 3.7, 4.1, 4.7, 6.0 mm (3.5, 4.5, 5.7mm platform sizes) cleared under K133339, K113753, K112160, K111889, K101880, K101977, and K072589.

Raw material blank

- InCoris Zi (ZrO2) by Sirona Dental Systems GmbH, L size blanks, cleared under K123664.

Software

Sirona Dental CAD/CAM System, by Sirona Dental Systems GmbH, cleared under K111421.

No change has been made in the software, its settings or configuration, as well as any modification in the workflow. Sirona inLab software or Sirona CEREC® Software are to be used to design the prosthesis structure according to the previous prosthetic planning. Therefore, the users are required to use the device models (3D models) and the workflow defined and validated by Sirona through K111421, according to the Instruction for Use of TruBase S.

Indication for Use

The TruBase S is a titanium component that is directly connected to endosseous dental implants to provide support for patient-specific 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 (3.5, 4.5, 5.7mm platform sizes)

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.

Summary of Technological Characteristics

Both the subject and the reference devices have the same indication of providing support for prostheses. All devices are pre-manufactured titanium bases made of titanium (Ti-6Al-4V ELI), designed to be used as a base when fabricating a CAD/CAM patient-specific superstructure and are compatible with the same CAD/CAM system and blocks of raw material. A clinician or dental laboratory equipped with the Sirona Dental CAD/CAM System will design and mill the patient-specific superstructure, which composes the final medical device after the bonding to TruBase S.

The subject devices differ from the primary predicate devices cleared under K151324 only in the portion of implant connection, which is specific for each manufacturer. The cementable portion is identical and compatible with the Sirona Dental CAD/CAM System and the blocks of raw material. In the end of this section a comparison between the features of subject device and its predicate devices is shown in a tabular format.

Comparison between Proposed Device and Predicates

Attributes	Proposed Device	Predicate Device	Reference Device #1	Reference Device #2	EQUIVALENCE DISCUSSION
Trade Name	TruBase S	Straumann® Variobase® for CEREC® (K151324)	Neodent Implant System Titanium Base for CEREC® (K160964)	Link Abutment for CEREC® (K160519)	
Indications for Use	The TruBase S is a titanium component that is directly connected to endosseous dental implants to provide support for patient-specific 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 (3.5, 4.5, 5.7mm platform sizes) 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.	The Straumann® Variobase® for CEREC® are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for CEREC® abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase® for CEREC® abutments are to be designed using Sirona inLab software (Version 3.65) or Sirona CEREC Software (Version 4.2) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.	The Titanium Base for CEREC is a titanium component that is placed over Neodent Implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for single-tooth screw-retained restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base for CEREC are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.	The Link Abutment for CEREC is titanium alloy abutments placed onto HIOSSEN dental implants to provide support for customized prosthetic restorations. Link Abutment for CEREC is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. • Link abutment for CEREC All digitally designed copings and/or crowns for use with the Link abutment for CEREC is to be scanned using Sirona CEREC AC or CEREC AF or CEREC AI, designed using Sirona inLab software (Version 3.65) or Sirona CEREC Software (Version 4.2) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit. CAD/CAM manufacturing/milling occurs at dental laboratories per the design limitations of the Sirona CEREC.	**Equivalent** The basic indication of providing support for prostheses is identical. All devices are CAD/CAM abutment design to be used as a base when fabricating a patient-specific superstructure. The subject devices are compatible with the same CAD/CAM System as the primary predicate device.
Abutment Diameter(s)	4.3, 5.3, 6.5 mm	4.5 to 7.0 mm	4.65 mm	4.5 mm	**Equivalent** Subject devices diameter is within the range of diameters for the primary predicate devices and does not represent a worst case in terms of performance.
Abutment Height(s)	4.7 mm	4.7 mm	4.7 mm	4.7 mm	**Identical**

Material of Abutment	Ti-6Al-4V ELI	Titanium-AluminumNiobium alloy (Ti-6Al-7Nb)	Titanium-aluminumvanadium alloy Ti-6Al-4V	Titanium Alloy	**Equivalent** The subject and reference devices are made of the same titanium alloy; the titanium alloy of the primary predicate device differs, but the strength of the materials is demonstrated via dynamic fatigue testing. Also, all materials are shown to be biocompatible.
Implant-to-Abutment Connection(s)	• Internal hex	RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit), and RC (Regular CrossFit)	Morse taper (CM) interface	Morse taper internal connection Mini (Hex, non-Hex) Regular (Hex, non-Hex)	**Equivalent** The implant-to-abutment connections of TruBase S and Straumann devices are not identical, but equivalent because of the compatibility with the identified Zimmer implant body.
Compatibility	Zimmer 3.5mm, 4.5mm, 5.7mm platform sizes	Straumann implant lines, as indicated by the implant-to abutment interfaces.	Morse taper (CM) implant lines of Neodent Implant System.	HIOSSEN dental implants; ETIII SA Fixture ETIII SA Ultra-Wide Fixture ETII SA Fixture	**Equivalent** The implant-to-abutment connections of TruBase S and Straumann devices are not identical, but equivalent because of the compatibility with the identified Zimmer implant body.
Retention	Screw-retained	Screw-retained or cement retained	Screw-retained	Screw-retained	**Equivalent** Subject device mode of attachment is more restrictive and is within the scope of the primary predicate device's mode of attachment.
Restorative Range of Angulation	Up to 20°	Up to 20°	Up to 20°	Up to 20°	**Identical** The restoration angulation is identical among the devices that use Sirona Dental CAD/CAM System

Material of Superstructure	inCoris ZI meso (K123664)	Zirconia IPS e-max CAD PMMA	Zirconia IPS e-max CAD	Currently available: inCoris ZI meso (K123664) Ivoclar IPS e.max CAD (K132209) Ivoclar Telio CAD (K093708)	**Equivalent** The range of materials cleared for use with the primary predicate and reference devices is within the scope of materials indicated for the subject devices.
Patient-Specific Design	CAD/CAM manufactured superstructures	CAD/CAM manufactured superstructures	CAD/CAM manufactured superstructures	CAD/CAM manufactured superstructures	**Identical**
Manufacturing work-flow	Sirona Dental CAD/CAM System	Sirona Dental CAD/CAM System	Sirona Dental CAD/CAM System	Per the Sirona CEREC MC X and MC XL milling systems	**Equivalent** The subject device manufacturing work-flow is the same of the primary predicate device workflow
Sterility	Delivered non-sterile.; To be sterilized by user after superstructure cementation, before placed in patient mouth.	Delivered non-sterile.; To be sterilized by user after superstructure cementation, before placed in patient mouth.	Delivered sterile by EO exposure. To be sterilized by user after superstructure cementation, before placed in patient mouth.	Delivered non-sterile.; To be sterilized by user after superstructure cementation, before placed in patient mouth.	**Equivalent** Although TruBase S and one reference device is provided in different sterilization conditions, all final abutments must be sterilized by steam before be placed in patient mouth.
End-User Sterilization	Moist steam sterilization	Moist steam sterilization	Moist steam sterilization	Moist steam sterilization	**Identical**

Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalence as 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 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.

Mechanical Testing

Mechanical 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. The fatigue limit demonstrates the substantial equivalence. The results of the fatigue test have met the criteria of the standard, ISO 14801:2016, and demonstrated the substantial equivalence with the predicate device.

Dimensional analysis and reverse engineering

Dimensional analysis and reverse engineering the OEM implant body, OEM implant abutment and OEM abutment fixation screw including all the connection platforms (implant-to-abutment and abutment-to-mesostructure) 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-to-mesostructure compatibility and has established substantial equivalency of the proposed device with predicate devices.

Software Verification and Validation Testing

The recommended software was considered as a "moderate" level of concern, since a failure or latent design flaw could directly result in minor injury to the patient or operator. Therefore, the subject TruBase S was verified and validated with respect to its functionality and design using the Sirona validated workflow. The recommended CAD/CAM System is the same used for the primary predicate device and

the validation performed was based on the validation presented by the manufacturer of the primary predicate device.
Note: TruAbutment makes no changes to the software, its setting or configuration, as well as no modification in the workflow defined and validated by Sirona per K111421. The Sirona software is recommended because of the compatibility of its existing 3D models with the subject device.
Clinical testing was not necessary to establish substantial equivalency of the device.

Conclusion: 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 devices. Therefore, TruBase S and its predicates are substantially equivalent.