June 4, 2021

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

Re: K201842
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: April 22, 2021
Received: May 4, 2021

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,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT 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)*
K201842

Device Name
TruBase S

Indications for Use *(Describe)*
TruBase S is a titanium component that is directly connected to endosseous dental implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for a screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible with the following systems:

• NobelActive (K102436, K071370, K133731): 3.0, 3.5, 4.3, 5.0, 5.5 (3.0, NP, RP, WP)

All digitally designed abutments and/or copings for use with TruBase S are intended to be sent to a TruAbutment-validated milling center for manufacture.

TruBase S is compatible with the following devices:

NobelActive (K102436, K071370, K133731)
Implant Body Diameter 3.0 / Implant Platform 3.0 / Connection Type: Internal Hex
Implant Body Diameter 3.5 / Implant Platform NP / Connection Type: Internal Hex
Implant Body Diameter 4.3 / Implant Platform RP / Connection Type: Internal Hex
Implant Body Diameter 5.0 / Implant Platform RP / Connection Type: Internal Hex
Implant Body Diameter 5.5 / Implant Platform WP / Connection Type: Internal Hex

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

K201842

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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: 06/03/2021

Primary Predicate Device/ Reference Devices:

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

Primary Predicate Device:

- TruAbutment DS, TruBase S (K201197) by TruAbutment Inc.

Reference Devices:

- Nobelactive 3.0 (K102436) By Nobel Biocare.
- Nobelactive Internal Connection Implant (K071370) By Nobel Biocare.
- Nobelactive Wide Platform (Wp) (K133731) By Nobel Biocare.

General Description

TruBase S

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. The system also includes a TruBase S Screw for fixation to the implant body.

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 (NobelActive 3.0, NP, RP, WP). The TruBase S Screws are composed of titanium alloy per ASTM F136.

They also feature:

- cylindrical shape
- hexagonal indexing at the apical end of the connection
- indexing guide in the cementable portion for coping fitting

CAD/CAM customized superstructure that composes the final abutmentis intended to be sent to a TruAbutment-validated milling center to be designed and milled, according to the prosthetic planning and patient clinical situation. The superstructure is cemented to the TruBase S in the lab. Use "RelyX Unicem 2Automix" as an adhesive extra orally to connect.

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

The following table shows the subject device abutment platform sizes for each of the OEM implant lines and sizes.

TruBase S is compatible with the following devices:

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
NobelActive (K102436, K071370, K133731)	3.0	10	36769	3.0	Internal Hex
		11.5	36770		
		13	36771		
		15	36772		
	3.5	10	34125	3.5 (NP)	
		11.5	34126		
		13	34127		
		15	34128		
	4.3	10	34131	3.9 (RP)	
		11.5	34132		
		13	34133		

		15	34134		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
	5.0	10	34137	3.9 (RP)	
		11.5	34138		
		13	34139		
		15	34140		
	5.5	7	37806	5.1 (WP)	
		8.5	37807		
		10	37808		
		11.5	37809		
		13	37810		

Raw material blanks

- InCoris Zi (ZrO2) by Sirona Dental Systems GmbH, L size blanks, (same as K201197).

Cement

- RelyX Unicem 2Automix by 3M ESPE, (same as K201197).
- Design Limitation for Zirconia

superstructure

Design parameter	Design Limit
Minimum and Maximum abutment angle (°)	0~15
Minimum and Maximum Cuff Height (mm)	0.5~5.0
Minimum and Maximum diameter at abutment/implant interface (∅, mm)	5.0~8.0
Minimum Thickness (mm)	0.4
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height) (mm)	4.0~6.0

Indication for Use

TruBase S is a titanium component that is directly connected to endosseous dental implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for a screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible with the following systems:

- NobelActive (K102436, K071370, K133731): 3.0, 3.5, 4.3, 5.0, 5.5 (3.0, NP, RP, WP)

All digitally designed abutments and/or copings for use with TruBase S are intended to be sent to a TruAbutment-validated milling center for manufacture.

TruBase S is compatible with the following devices:

NobelActive (K102436, K071370, K133731)
Implant Body Diameter 3.0 / Implant Platform 3.0 / Connection Type: Internal Hex
Implant Body Diameter 3.5 / Implant Platform NP / Connection Type: Internal Hex
Implant Body Diameter 4.3 / Implant Platform RP / Connection Type: Internal Hex
Implant Body Diameter 5.0 / Implant Platform RP / Connection Type: Internal Hex
Implant Body Diameter 5.5 / Implant Platform WP / Connection Type: Internal Hex

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 diameter and connection type. Comparison demonstrating Substantial Equivalence follows at the end of this section.

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruBase S	TruBase S (K201197)
Indications for Use	TruBase S is a titanium component that is directly connected to endosseous dental implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for a screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible with the following systems: • NobelActive (K102436, K071370, K133731): 3.0, 3.5, 4.3, 5.0, 5.5 (3.0, NP, RP, WP) All digitally designed abutments and/or copings for use with TruBase S are intended to be sent to a TruAbutment-validated milling center for manufacture. TruBase S is compatible with the following devices:	TruBase S is a titanium component that is directly connected to endosseous dental implants to provide support for custom 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 3.1mmD Dental Implant System (K142082) Screw Vent® and Tapered Screw Vent® (K013227) TruBase S is intended to be sent to a TruAbutment-validated milling center for manufacture. TruBase S is compatible with the

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruBase S	TruBase S (K201197)
	NobelActive (K102436, K071370, K133731) Implant Body Diameter 3.0 / Implant Platform 3.0 / Connection Type: Internal Hex Implant Body Diameter 3.5 / Implant Platform NP / Connection Type: Internal Hex Implant Body Diameter 4.3 / Implant Platform RP / Connection Type: Internal Hex Implant Body Diameter 5.0 / Implant Platform RP / Connection Type: Internal Hex Implant Body Diameter 5.5 / Implant Platform WP / Connection Type: Internal Hex	following devices: Zimmer 3.1mmD Dental Implant System(K142082) Implant Body Diameter 3.1/ Implant Platform Diameter 2.9 / Internal Hex Screw Vent® and Tapered Screw Vent® (K013227) Implant Body Diameter 3.7/ Implant Platform Diameter 3.5 / Internal Hex Implant Body Diameter 4.1/ Implant Platform Diameter 3.5 / Internal Hex Implant Body Diameter 4.7/ Implant Platform Diameter 4.5 / Internal Hex Implant Body Diameter 6.0/ Implant Platform Diameter 5.7 / Internal Hex
CAD Design Limits	Maximum Angulation 0~15° Maximum Cuff Height 0.5~5mm Minimum Diameter Ø 5.0~ Ø 8.0mm Minimum Thickness 0.4mm Minimum Post Height 4~6mm	Maximum Angulation 0~15° Maximum Cuff Height 0.5~5mm Minimum Diameter Ø 5.0~ Ø 8.0mm Minimum Thickness 0.4mm Minimum Post Height 4~6mm

Attributes	Proposed Device	Primary Predicate Device
Trade Name	TruBase S	TruBase S (K201197)
Abutment Diameter (s)	Engaging: 3.5, 4.0, 4.5, 4.6, 5.5mm Non-Engaging: 3.5, 4.0, 4.5, 4.6, 5.5mm	Engaging: 3.5, 3.8, 4.5, 5.7mm Non-Engaging: 3.5, 4.3, 4.5, 5.3, 5.7, 6.5mm
Abutment Height (s)	6.7~10.7mm	4.7mm
Material of Abutment	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Implant-to-Abutment Connection(s)	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.
Type of Retention	Screw-retained	Screw-retained
Material of Superstructure	InCoris Zi	InCoris ZI
Manufacturing processes	TruAbutment-validated milling center	TruAbutment-validated milling center
End-User Sterilization	Moist steam sterilization	Moist steam sterilization

Substantial Equivalence Discussion

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.

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. Provided tables are comparing the Indications for Use Statements and the technological characteristics of the subject device and the primary predicate device.

The Indications for Use Statement (IFUS) for the subject device (TruBase S) is substantially equivalent in intended use to the primary predicate device (K201197). All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible.

The Indications for Use Statement (IFUS) for the subject device (TruBase S) is substantially equivalent to that of the primary predicate device (K201197). Slight differences in the language of the subject device and primary predicate device Indications for Use statements do not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function.

The other minor differences are related to the compatible OEM implant lines. None of these minor differences impact substantial equivalence because all IFUS express equivalent intended to use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

Also, the primary predicate device follows the same digital workflow and utilizes the same materials (Ti-6Al-4V ELI) and inCoris ZI, as the subject device system.

The subject device and the predicate device design parameter are substantially equivalent.

Design parameter	Subject Device (K201842)	Predicate Device (K201197)
Minimum and Maximum abutment angle (°)	0~15	0~15
Minimum and Maximum Cuff Height (mm)	0.5~5.0	0.5~5.0
Minimum and Maximum diameter at abutment/implant interface (∅, mm)	5.0~8.0	5.0~8.0

Design parameter	Subject Device (K201842)	Predicate Device (K201197)
Minimum Thickness (mm)	0.4	0.4
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height) (mm)	4.0~6.0	4.0~6.0

Mechanical performance testing was performed according to ISO 14801:2016. For compatible OEM implant lines, worst-case constructs were subjected to static compression and compression fatigue testing. The fatigue limit data for all other implant lines demonstrated the construct strengths to be sufficient for their intended use.

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 (K201197) 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.

Comparative fatigue testing of the subject and predicate devices was conducted in accordance with ISO 14801 and 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 OEM implant body, OEM 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.

Conclusion

The 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 device. Therefore, TruBase S and its predicate are substantially equivalent.