



Food and Drug Administration
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September 11, 2015

Straumann USA LLC
c/o Ms. Sheila Hemeon-Heyer
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, Massachusetts 01002

Re: K151324

Trade/Device Name: Straumann® Variobase® for CEREC®, Abutment Models RN, WN,
RC, NC

Regulation Number: 21 CFR 872.3630

Regulation Name: Endosseous Dental Implant Abutment

Regulatory Class: II

Product Code: NHA

Dated: August 12, 2015

Received: August 13, 2015

Dear Ms. Hemeon-Heyer:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

 Tina
Kiang -S

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

Indications for Use

510(k) Number (if known)
K151324

Device Name
Straumann® Variobase® for CEREC®, Abutment Models RN, WN, RC, NC

Indications for Use (Describe)

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 higher) or Sirona CEREC Software (Version 4.2 or higher) and manufactured using a Sirona CEREC or inLab MC X 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.

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510(k) Summary

K151324

6.1 Submitter's Contact Information

Submitter Name: Straumann USA, LLC (on behalf of Institut Straumann
AG) Address: 60 Minuteman Road
Andover, MA 01810
Phone Number: 1-978-747-2575
Fax Number: 1-978-747-0023
Contact Person: Christopher Klaczyk
Date of Summary: September 10, 2015

6.2 Name of the Device

Trade Name: Straumann® Variobase® for CEREC®, Abutment Models RN, WN, RC, NC
Common Name: Dental Implant Abutment
Classification Name: Endosseous Dental Implant Abutment
Regulation & Class: 21 CFR §872.3630, Class II
Product Code: NHA

6.3 Predicate Devices

Primary Predicate:

- K142890, Straumann® Variobase® Abutments, Models NNC, RN, WN, RC, NC

Reference Predicate(s):

- K100152, Sirona Dental CAD/CAM System (introduction of the Sirona SSO series Ti-bases compatible with the Straumann Tissue Level implants and introduction of the CEREC MC X and MC XL and inLab MC X and MC XL mills)
- K111421, Sirona Dental CAD/CAM System (introduction of the Sirona SBL series Ti-bases compatible with the Straumann Bone Level implants)

6.4 Device Description

The Straumann® Variobase® for CEREC® abutments provide the interface for copings or crowns designed and milled using the Sirona CEREC system with four of the Straumann dental implant platforms: RN (Regular Neck), WN (Wide Neck), RC (Regular CrossFit®), and NC (Narrow CrossFit®). The Straumann® Variobase® for CEREC® abutments are pre-manufactured (stock) abutments, sometimes referred to as "Ti-bases," made from a titanium-aluminum-niobium (TAN) alloy. The coronal portion is designed to interface with the pre-machined mounting hole in the milling blanks compatible with the Sirona

Straumann® Variobase® for CEREC® Traditional 510(k)

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CEREC MC X and MC XL prosthetic milling systems, and the base portion is available in four models to fit the four Straumann® dental implant platforms listed above. The new components introduced in this 510(k) are shown below.

Straumann® Variobase® for CEREC® Abutments			
			
RN	WN	RC	NC

Catalog Number	Description
022.0019	RN Variobase® for CEREC®
022.0020	WN Variobase® for CEREC®
022.0024	RC Variobase® for CEREC®
022.0025	NC Variobase® for CEREC®
022.0045	RN/WN Basal screw for Variobase®*

The Straumann® Variobase® for CEREC® abutments are compatible with the following previously cleared materials:

- inCoris ZI, L size blank (Sirona inCoris ZI meso zirconium dioxide, ZrO₂) cleared to market per K062509 and K123664
- IPS e.max CAD Abutment Solutions (Ivoclar IPS e.max CAD lithium disilicate glass-ceramic, LS₂) cleared to market per K132209
- Telio CAD (Ivoclar Telio CAD polymethylmethacrylate, PMMA) cleared to market per K093708

The Straumann® Variobase® for CEREC® abutments are compatible with copings and crowns fabricated using the following previously cleared mills:

- Sirona Dental CAD/CAM System (introduction of the Sirona SSO series Ti-bases compatible with the Straumann Tissue Level implants and introduction of the CEREC MC X and MC XL and inLab MC X and MC XL mills) cleared to market per K100152
- Sirona Dental CAD/CAM System (introduction of the Sirona SBL series Ti-bases compatible with the Straumann Bone Level implants) cleared to market per K111421

Straumann has verified that the functionality necessary to design and produce abutments compatible with the Straumann Variobase for CEREC abutments (as well as the Sirona SSO and SBL series Ti-bases) has been present in the Sirona CEREC Software since

version 4.2 (released May 2013) and in the Sirona inLab Software since version 3.65 (released January 2012). Copings and crowns designed using these or more recent versions of the Sirona software, within the design limits as defined within the design software, are compatible with the Straumann Variobase for CEREC abutments.

6.5 Indications For Use

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 higher) or Sirona CEREC Software (Version 4.2 or higher) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.

6.6 Substantial Equivalence and Performance Testing

The Straumann® Variobase® for CEREC® are made of the same TAN alloy material and the same base design as primary predicate Straumann® Variobase® Abutments previously cleared for the Straumann® implant platforms RN, WN, RC and NC. The only difference is that the coronal portion of these abutments has been designed to interface with the milling blanks used to create copings and crowns with the Sirona CEREC® CAD/CAM system. The new design assures dimensional matching of the CEREC® restorations with the Straumann Variobase for CEREC® abutments and provides an interlocking feature to augment the cemented adhesion of the restoration onto the abutment.

The subject Straumann Variobase for CEREC abutments are functionally equivalent to the reference predicate Sirona SSO series Ti-base abutments previously cleared to market per K100152 and the reference predicate Sirona SBL series Ti-base abutments previously cleared to market per K111421. The Sirona SSO series Ti-bases have been shown by Sirona to be compatible with Straumann Tissue Level implants and the Sirona SBL series Ti-bases have been shown by Sirona to be compatible with Straumann Bone Level implants. The coronal geometry of the subject devices is equivalent to the coronal geometry of the reference predicates, therefore copings and crowns fabricated using the Sirona software and milling systems will be compatible with the subject devices.

The following performance testing was submitted in this 510(k) to support substantial equivalence:

- Dimensional verification using CEREC® e.max blocks, which confirmed the appropriate fit of the milled coping on the abutment
- Worst case dynamic fatigue testing demonstrating compliance with the
- minimum required fatigue properties of the Straumann® Variobase® for CEREC®
- abutments with cemented e.max CAD/CAM coping
- Process validation of the Straumann® Variobase® for CEREC® within the Sirona CEREC® InLab workflow

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- Sterilization validation according to ISO 17665-1, ISO/TR 17665-2 and ANSI/AAMI ST79

There have been no changes to the materials, packaging, or recommended sterilization method/parameters for these devices as compared to the primary predicate devices.

Straumann® Variobase® for CEREC® Traditional 510(k)

Section 6: 510(k) Summary

FEATURE	SUBJECT DEVICE Straumann Variobase for CEREC Abutments	PRIMARY PREDICATE Straumann Variobase Abutments (K142890)	EQUIVALENCE DISCUSSION
Intended Use	Intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns.	Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations.	Substantially equivalent
Indications for Use	<p>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.</p> <p>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 higher) or Sirona CEREC Software (Version 4.2 or higher) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.</p>	<p>The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.</p> <p>All digitally designed copings and/or crowns for use with the Straumann® Variobase™ Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.</p>	Different workflows used to design and fabricate the restorations. Coronal aspect of proposed device is designed to interface with copings/crowns fabricated from milling blanks containing pre-machined holes for use with the CEREC CAD/CAM system. Substantial equivalence based on design validation testing.

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FEATURE	SUBJECT DEVICE Straumann Variobase for CEREC Abutments	PRIMARY PREDICATE Straumann Variobase Abutments (K142890)	EQUIVALENCE DISCUSSION
Contraindications	Patients with known allergies or hypersensitivity to chemical ingredients of the following materials used: titanium (Ti), titanium alloy Ti6Al7Nb (titanium-aluminum-niobium or TAN)	Allergies or hypersensitivity to materials used: Titanium alloy Ti-6Al-7Nb (titanium- aluminum-niobium or TAN).	Same
Ti-base Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Same
Abutment Diameter (base)	4.5 mm – 7.0 mm	3.8 mm – 7.0 mm	Substantially equivalent Proposed device models do not include NNC (3.8 mm dia)
Abutment Height	4.7 mm	3.5 – 4.5 mm	Substantially equivalent
Coping/ Crown Material	Compatible with any milling blanks cleared for use with the CEREC MC X and MC XL milling systems (i.e., containing the pre-machined mounting hole). Currently available: inCoris ZI meso (K123664) Ivoclar IPS e.max CAD (K132209) Ivoclar Telio CAD (K093708)	<u>Traditional Workflow:</u> Type 4 Metals (ISO 22674) IPS e.max® Press Ceramic <u>Digital Workflow:</u> polycon® ae (temporary) zerion® (permanent) IPS e.max® CAD Ceramic (permanent) coron® (permanent)	Substantially equivalent All materials to be used for coping/crown have previously been cleared and are not the subject of this 510(k).
Design Workflow	Per the Sirona CEREC InLab, software version 3.6 or later	Wax-up or Open CAD	Substantially equivalent

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FEATURE	SUBJECT DEVICE Straumann Variobase for CEREC Abutments	PRIMARY PREDICATE Straumann Variobase Abutments (K142890)	EQUIVALENCE DISCUSSION
Manufacturing Workflow	Per the Sirona Cerec MC X and MC XL milling systems	Traditional casting or pressing or Straumann Milling	Substantially equivalent
Mode of Attachment	Screw-retained or cement retained	Screw-retained or cement retained	Same
Reusable	No	No	Same

6.7 Conclusion

The documentation submitted in this premarket notification demonstrates that the Straumann® Variobase® for CEREC® abutments are substantially equivalent to the primary predicate Straumann® Variobase® Abutments and the reference predicate Sirona Ti-base devices previously cleared as being compatible with the implants of the Straumann Dental Implant System.