DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 16, 2015

Straumann USA, LLC
Mr. Christopher Klaczyk
Director, Regulatory and Clinical Affairs
60 Minuteman Road
Andover, Massachusetts 01810

Re: K150899
Trade/Device Name: Straumann® CARES® Titanium Alloy (TAN) Abutment
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 Mr. Klaczyk:

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*
K150899

Device Name

Straumann® CARES® Titanium Alloy (TAN) Abutments

Indications for Use *(Describe)*

The Straumann CARES® TAN abutments are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/ screw-retained.

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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5. **510(k) Summary**

K150899

Submitter:	Straumann USA, LLC (on behalf of Institut Straumann AG) 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052
Contact Person:	Christopher Klaczyk Director of Regulatory Affairs and Clinical Research
Date Prepared:	August 27, 2015
Product Code(s):	NHA (21 CFR 872.3630)
Device Class:	II (21 CFR 872.3630)
Classification Panel:	Dental
Classification Name:	Endosseous dental implant abutment (21 CFR 872.3630)
Proprietary Name:	Straumann® CARES® Titanium Alloy (TAN) Abutments
Primary Predicate Device:	K061277 – Straumann RN CARES Ceramic Coping
Reference Predicate Device(s):	K072151 – P.004 RC CARES Titanium and Ceramic Abutment K081005 – P.004 NC CARES Titanium and Ceramic Abutment
Reference Device(s):	K052272 – Straumann RN CARES Titanium Abutment K082764 – Straumann CARES WN Titanium Coping
Device Description:	Straumann® CARES® TAN Abutments are used for the restoration of Straumann dental implants of different types, endosteal diameters, lengths. The abutments are available with interface geometry compatible with the bone level NC (3.3 mm) and RC (4.1 mm) and the tissue level RN (3.3 mm, 4.1 mm) and WN (4.8 mm) implants. The proposed CARES® TAN abutments are provided in a set that contains the individualized abutment and a corresponding basal screw. The Straumann CARES TAN Abutments allow for individual customization regarding function and esthetics. Straumann CARES TAN Abutments are designed by the customer either by means of a traditional wax-up abutment that is subsequently

scanned or by scanning of the intraoral situation and designing of the shape by using software such as Straumann CARES Visual. The design data is then transferred to Straumann where the fabrication of the customized abutment is carried out. Design limits are as follows:

	Predicate Ceramic	***Subject TAN*** *RC, RN 4.1, WN*	***Subject TAN*** *NC, RN 3.3*
Parameter	***Limit***	***Limit***	***Limit***
Max. Angulation	30°	30°	0°
Emergence Offset	0.1 mm	0.1 mm	0.1 mm
Emergence Angle	65°	65°	65°
Min. Thickness	0.5 mm	0.4 mm	0.4 mm
Smooth Distance	0.5 mm	0.5 mm	0.5 mm

The Straumann CARES TAN Abutments can be directly veneered or a dental restoration like a crown or bridge can be cemented to the abutments.

Indications For Use: The Straumann CARES® TAN abutments are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/ screw-retained.

Intended Use: Prosthetic components connected to the implant are intended for use as an aid in prosthetic rehabilitation.

Materials: The subject devices are produced from titanium-6aluminum-7niobium alloy (TAN) conforming to ISO 5832-11.

Technological Characteristics: See table below.

FEATURE	SUBJECT Straumann® CARES® TAN Abutments	PREDICATE Straumann® CARES® Ceramic Abutments (K061277, K072151, K081005)	REFERENCE Straumann® CARES® Titanium Abutments (K052272, K072151, K081005, K082764)	Equivalence Discussion
Indications for Use	The Straumann CARES® TAN abutments are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/ screw-retained.	Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges and overdentures. The P.004 NC CARES Ceramic Abutment is indicated for single tooth replacements and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw retained.	Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges and overdentures. The P.004 NC CARES Titanium Abutment is indicated for cemented restoration. The abutment can be used in single tooth replacements and multiple tooth restorations.	**Equivalent** The indicated uses of the subject and ceramic predicate devices are equivalent, including the ability to be directly veneered; the opening paragraph for the ceramic abutments does not materially change the indications. The predicate titanium abutments are not indicated for direct veneering.
Abutment Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb, TAN)	Zirconium dioxide ceramic (ZrO_2)	Commercially pure grade 4 titanium	**Equivalent** Different materials, both meeting accepted standards for use in dental restorations

FEATURE	SUBJECT Straumann® CARES® TAN Abutments	PREDICATE Straumann® CARES® Ceramic Abutments (K061277, K072151, K081005)	REFERENCE Straumann® CARES® Titanium Abutments (K052272, K072151, K081005, K082764)	Equivalence Discussion
Abutment Apical Design	Engaging **BoneLevel** Narrow CrossFit (NC) Regular CrossFit (RC) **Tissue Level** Regular Neck (RN) Wide Neck (WN)	Engaging **BoneLevel** Narrow CrossFit (NC) Regular CrossFit (RC) **Tissue Level** Regular Neck (RN)	Engaging **BoneLevel** Narrow CrossFit (NC) Regular CrossFit (RC) **Tissue Level** Regular Neck (RN) Wide Neck (WN)	**Equivalent** The subject TAN abutments employ the same implant-to-abutment platforms as the titanium predicates. The ceramic predicates do not include the WN platform.
Abutment Coronal Design	CADCAM design process. Designs controlled by material-specific design limits in the CARES Visual CAD software, model verification performed by the CAM software and milling blank dimensions used by the Straumann milling center.	CADCAM design process. Designs controlled by material-specific design limits in the CARES Visual CAD software, model verification performed by the CAM software and milling blank dimensions used by the Straumann milling center.	CADCAM design process. Designs controlled by material-specific design limits in the CARES Visual CAD software, model verification performed by the CAM software and milling blank dimensions used by the Straumann milling center.	**Identical**

FEATURE	SUBJECT Straumann® CARES® TAN Abutments	PREDICATE Straumann® CARES® Ceramic Abutments (K061277, K072151, K081005)	REFERENCE Straumann® CARES® Titanium Abutments (K052272, K072151, K081005, K082764)	Equivalence Discussion
CAD Design Limits	**RC, Ø4.1RN, WN platforms:** Max. Angulation 30° Emergence Offset 0.1 mm Emergence Angle 65° Min. Thickness 0.4 mm Smooth Distance 0.5 mm **NC, Ø3.3RN platforms:** Max. Angulation 0° Emergence Offset 0.1 mm Emergence Angle 65° Min. Thickness 0.4 mm Smooth Distance 0.5 mm	**All platforms:** Max. Angulation 30° Emergence Offset 0.1 mm Emergence Angle 65° Min. Thickness 0.5 mm Smooth Distance 0.5 mm	**All platforms:** Max. Angulation 30° Emergence Offset 0.1 mm Emergence Angle 65° Min. Thickness 0.33 mm Smooth Distance 0.5 mm	**Equivalent** The applied limits are identical with the exception of minimum wall thickness which is a function of the material properties. The minimum wall thickness for TAN is within the range defined by the ceramic and titanium predicates.
Directly Veneerable?	Yes	Yes	No	**Equivalent** The veneering technique for the subject devices requires an initial firing to form the oxide layer, otherwise it is identical to that for the ceramic abutments.

Performance Data: Per *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments* dated May 12, 2004, the substantial equivalence of the subject device(s) are satisfactorily addressed via bench studies. Dynamic fatigue test data consistent with FDA guidance and ISO 14801 have been provided in support of this submission.

Veneer testing consistent with ISO 9693-1 has been provided in support of this submission.

Corrosion resistance testing performed per ISO 10271 has been provided in support of this submission.

Biocompatibility testing per ISO 10993-5 (cytotoxicity) and ISO 10993-18 (chemical analysis) have been submitted in support of this submission.

Conclusions: Based upon our assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate devices.