DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 5, 2015

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

Re: K151157
Trade/Device Name: Straumann® Variobase® Abutment for Bars/bridges
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: July 2, 2015
Received: July 6, 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)*
K151157

Device Name

Straumann® Variobase Abutments for Bridges/Bars

Indications for Use *(Describe)*

Straumann® Variobase™ prosthetic components directly connected to the endosseous dental implants are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration (bridge or over-denture) can be cemented on the Straumann® Variobase™ prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. They may not be placed into occlusion. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated.

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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K151157

510(k) Summary

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 4, 2015

Product Code(s):
NHA (21 CFR 872.3630)

Device Class:
II (21 CFR 872.3630)

Classification Panel:
Dental

Classification Name:
Endosseous dental abutment (21 CFR 872.3630)

Proprietary Name:
Straumann® Variobase® Abutment for Bridges/Bars

Predicate Device(s):
- K142890, Straumann Variobase Abutments

Reference Device(s):
- K132219, Straumann Variobase Abutments
- K120822, Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC
- K080239, Straumann Bone Level Multibase Abutments
- K990342, Straumann synOcta Prosthetics
- K140737, Straumann Screw-Retained Bridge and Bar

Device Description:
The Straumann Variobase Abutments for Bars & Bridges are non-engaging abutments made from Ti-6Al-7Nb (TAN) that support a bridge or bar reconstruction (framework or full contour) on two or more dental implants. The corresponding basal screw is delivered with the abutment for connecting the abutment to the implant. A dental laboratory technician designs and manufactures the bridge/bar reconstruction via their preferred workflow using traditional or CAD/CAM methods.

Indications For Use:	Straumann® Variobase® prosthetic components directly connected to the endosseous dental implants are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration (bridge or overdenture) can be cemented on the Straumann® Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. They may not be placed into occlusion. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated.
Intended Use:	Straumann® Variobase® abutments are intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as bridges and over-dentures.
Materials:	The subject devices are produced from titanium-6aluminum-7niobium alloy (TAN). This is the same material as for the predicate devices cleared to market per premarket notification submissions K120822, K132219 and K142890.
Technological Characteristics:	The subject Straumann Variobase Abutments for Bridge/Bar devices have the same Indications For Use, Implant-to-Abutment platforms, materials, packaging and dynamic fatigue performance as the identified Straumann Variobase Abutment predicate devices. The subject devices differ in that they do not include the engaging features of the implant-to-abutment interface design allowing full axial rotation and the coronal aspect takes a form better suited to multi-unit restorations.

FEATURE	Straumann® Variobase® Abutments for Bridges/Bars Subject Submission	Primary Predicate Straumann® Variobase® Abutments (K142890)	Reference Devices Straumann® Multibase (K080239) and synOcta (K990342) Abutments	Equivalence Discussion
Indications for Use	Straumann® Variobase® prosthetic components directly connected to the endosseous dental implants are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration (bridge or over-denture) can be cemented on the Straumann® Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. They may not be placed into occlusion. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated.	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.	Not applicable	**Equivalent** The basic indication of providing support for prostheses is identical. Where the predicate is indicated for both single-unit and multi-unit restorations, the subject devices are only suitable for multi-unit restorations. This limited indication is within the scope of the indication of the predicate devices.
Abutment Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Not applicable	**Identical**
Abutment Diameter	4.2 – 7.0 mm	3.8 – 7.0 mm	Not applicable	**Equivalent** Subject device diameters are within the range of diameters for the predicate device.

FEATURE	Straumann® Variobase® Abutments for Bridges/Bars Subject Submission	Primary Predicate Straumann® Variobase® Abutments (K142890)	Reference Devices Straumann® Multibase (K080239) and synOcta (K990342) Abutments	Equivalence Discussion
Abutment Height	3.5 – 5.2 mm	3.5 – 4.5 mm	Not applicable	**Equivalent** The subject devices have the same minimum height as the Variobase predicates. Performance of the taller subject device is addressed via bench testing.
Abutment Apical Design	Non-engaging Morse taper	Engaging CrossFit® and Morse taper	Not applicable	**Equivalent** The Morse taper portion of both the subject and Variobase predicate devices are identical. Non-engaging abutments are necessary so as not to introduce mechanical constraints in the framework that would affect fit.
Abutment Coronal Design	10° or15° conical taper	Straight wall with detents	6° conical taper (K990342) 30° conical taper (K080239)	**Equivalent** The conic taper of the subject devices is within the range established by the synOcta and Multibase predicates.

FEATURE	Straumann® Variobase® Abutments for Bridges/Bars Subject Submission	Primary Predicate Straumann® Variobase® Abutments (K142890)	Reference Devices Straumann® Multibase (K080239) and synOcta (K990342) Abutments	Equivalence Discussion
Restoration Material	Materials cleared by the FDA under 21 CFR 872.6660 or exempt materials as described under 21 CFR 872.3060 (Noble metal alloys) and 21 CFR 872.3710 (Base metal alloys)	Traditional Workflow: Type 4 Metals (ISO 22674) IPS e.max® Press Ceramic Digital Workflow: polycon® ae (temporary) zerion® (permanent) IPS e.max® CAD Ceramic (permanent) coron® (permanent)	Not applicable	**Equivalent** The range of materials cleared for use with the predicate devices is within the scope of materials indicated for the subject devices.
Design Workflow	Wax-up or Open CAD Exempt from pre-market notification according to 21 CFR 807.85(a)(1).	Wax-up or Open CAD	Not applicable	**Identical**
Manufacturing Workflow	Traditional casting, pressing or Straumann Milling Center Exempt from pre-market notification according to 21 CFR 807.85(a)(1).	Traditional casting, pressing or Straumann Milling Center	Not applicable	**Identical**
Mode of Attachment	Screw-retained or cement retained	Screw-retained or cement retained	Not applicable	**Identical**
Reusable	No	No	Not applicable	**Identical**

Discussion of Substantial Equivalence:	The basic indication of providing support for prostheses is identical. Where the predicate is indicated for both single-unit and multi-unit restorations, the subject devices are only suitable for multi-unit restorations. This limited indication is within the scope of the indication of the predicate devices. Subject device diameters are within the range of diameters for the predicate devices. The subject devices have the same minimum height as the Variobase predicates. Performance of the taller subject device is addressed via bench testing. The Morse taper portion of both the subject and Variobase predicate devices are identical. Non-engaging abutments are necessary so as not to introduce mechanical constraints in the framework that would affect fit. The conic taper of the subject devices is within the range established by the synOcta and Multibase predicates. The bonding surface areas for the subject devices are consistent with those of the predicate. The range of materials cleared for use with the predicate devices is within the scope of materials indicated for the subject devices.
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 referenced 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.