July 17, 2018

Institut Straumann AG
Jennifer Jackson
Director, Regulatory Affairs and Quality
60 Minuteman Road
Andover, Massachusetts 01810

Re: K173968
Trade/Device Name: Straumann® Variobase™ for Bridge/Bar Cylindrical
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 14, 2018
Received: June 18, 2018

Dear Jennifer Jackson:

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 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: January 31, 2017

See *PRA Statement below.*

510(k) Number *(if known)*

K173968

Device Name

Straumann® Variobase™ for Bridge/Bar Cylindrical

Indications for Use *(Describe)*

Straumann® Variobase™ for Bridge/Bar Cylindrical prosthetic components directly connected to the endosseous dental implants are indicated for use as an aid in prosthetic rehabilitations. The patient-specific prosthetic restoration (bridge or over-denture) can be cemented on the Straumann® Variobase™ for Bridge/Bar Cylindrical 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. Temporary restorations are indicated to be placed out of occlusion. Straumann® Variobase™ for Bridge/Bar Cylindrical and patient-specific restorations may be placed into occlusion when the implant is fully osseointegrated.
All digitally designed Straumann® Variobase® for Bridge/Bar Cylindrical prosthetic components are intended to be sent to Straumann for manufacture at a validated milling center.

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

Submitter's Contact Information

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: Jennifer Jackson
Director, Regulatory Affairs & Quality

Prepared By: Dr. Gordon Dodds
Manager Design Control QM
Etkon GmbH

Date Prepared: July 16, 2018

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

Device Class: II (21 CFR 872.3630)

Classification Panel: Dental

Name of the Device

Classification Name: Endosseous dental implant abutment (21 CFR 872.3630)

Proprietary Name: Straumann® Variobase™ for Bridge/Bar Cylindrical

Predicate Device(s):

Predicate Device(s):

- K151157 Straumann Variobase for Bridge/Bar

Reference Device(s):

- K142890 Straumann Variobase Abutments
- K120822 Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC
- K132844 Straumann CARES Bone Level Screw Retained Bars, Straumann CARES Bone Level Screw Retained Bridges

- K041295 - RN Synocta UCLA Gold Abutment for the Straumann Dental Implant

Device Description

The Straumann® Variobase™ for Bridge/Bar Cylindrical, see Figure 1 and Table 1, are non-engaging (without rotational lock) 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.

Figure 1 Straumann Variobase for Bridge/Bar Cylindrical

Table 1 - Listing of devices

Device Name	Device Number
Straumann® NC Variobase™ for Bridge/Bar Cylindrical	022.0110 / 010.6085
Straumann® RC Variobase™ for Bridge/Bar Cylindrical	022.0111 / 010.6086
Straumann® RN Variobase™ for Bridge/Bar Cylindrical	048.378 / 010.6083
Straumann® WN Variobase™ for Bridge/Bar Cylindrical	048.379 / 010.6084
Straumann® NNC Variobase™ for Bridge/Bar Cylindrical	048.377 / 010.6082

Intended Use:

Straumann® Variobase™ for Bridge/Bar Cylindrical are intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as bridges and over-dentures

Indications For Use

Straumann® Variobase™ for Bridge/Bar Cylindrical prosthetic components directly connected to the endosseous dental implants are indicated for use as an aid in prosthetic rehabilitations. The patient-specific prosthetic restoration (bridge or over-denture) can be cemented on the Straumann® Variobase™ for Bridge/Bar Cylindrical 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. Temporary restorations are indicated to be placed out of occlusion. Straumann® Variobase™ for Bridge/Bar Cylindrical and patient-specific restorations may be placed into occlusion when the implant is fully osseointegrated.
All digitally designed Straumann® Variobase® for Bridge/Bar Cylindrical prosthetic components are intended to be sent to Straumann for manufacture at a validated milling center.

Technological Chracteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in the following table.

Table 2: Substantial Equivalence Comparison

FEATURE	Subject Device Straumann® Variobase™ for Bridge/Bar Cylindrical Subject Submission	Predicate Device Straumann® Variobase™ Abutments for Bridge/Bar (K151157)	Reference Predicate Devices Straumann® Variobase™ Abutments (K120822, K142890) Straumann® Screws (K132844, K041295)	Equivalence Discussion
Indications for Use	Straumann® Variobase™ for Bridge/Bar Cylindrical prosthetic components directly connected to the endosseous dental implants are indicated for use as an aid in prosthetic rehabilitations. The patient-specific prosthetic restoration (bridge or over-denture) can be cemented on the Straumann® Variobase™ for Bridge/Bar Cylindrical 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. Temporary restorations are indicated to be placed out of occlusion. Straumann® Variobase™ for Bridge/Bar Cylindrical and patient-specific restorations may be placed into occlusion when the implant is fully osseointegrated. All digitally designed Straumann® Variobase® for Bridge/Bar Cylindrical prosthetic components are intended to be sent to Straumann for manufacture at a validated milling center.	Straumann® Variobase® prosthetic components directly or indirectly connected to the endosseous dental implant are intended 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.	Not applicable	**Identical** Section regarding production methods has been added. The same production methods are used for the predicate device.
Abutment Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Not applicable	**Identical**

FEATURE	Subject Device Straumann® Variobase™ for Bridge/Bar Cylindrical Subject Submission	Predicate Device Straumann® Variobase™ Abutments for Bridge/Bar (K151157)	Reference Predicate Devices Straumann® Variobase™ Abutments (K120822, K142890) Straumann® Screws (K132844, K041295)	Equivalence Discussion
Abutment Diameter	4.5 – 7.0 mm	4.2 – 7.0 mm	Not applicable	**Equivalent** The subject device NC interface is 0.3 mm wider, and gives more support
Abutment Height	3.5 – 4.5 mm	3.5 – 4.5 mm	Not applicable	**Identical**
Abutment Apical Design	Non-engaging (no rotational lock) Morse taper	Non-engaging (no rotational lock) Morse taper	Not applicable	**Identical**
Abutment Coronal Design	Straight wall with detents	10° or15° conical taper	K120822, K142890 - Straight wall with detents	**Equivalent** The coronal design is identical to the reference predicate devices and has the equivalent function as the predicate devices.
Basal Screw Design	NC/RC Conical Head Screw Bone Level RN/WN Conical Head Screw Tissue Level		K132844, K041295 - NC/RC Conical Head Screw Bone Level RN/WN Conical Head Screw Tissue Level	**Identical**

FEATURE	Subject Device Straumann® Variobase™ for Bridge/Bar Cylindrical Subject Submission	Predicate Device Straumann® Variobase™ Abutments for Bridge/Bar (K151157)	Reference Predicate Devices Straumann® Variobase™ Abutments (K120822, K142890) Straumann® Screws (K132844, K041295)	Equivalence Discussion
Restoration Types Supported	Patient-specific prosthetic bridge or over-denture	Patient-specific prosthetic bridge or over-denture	Not applicable	**Identical**
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)	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)	Not applicable	**Identical**
Design Workflow	Wax-up or CAD	Wax-up or CAD	Not applicable	**Identical**
Manufacturing Workflow	Traditional casting or Straumann Milling Center	Traditional casting, pressing or Straumann Milling Center	Not applicable	**Identical**
Mechanical Stability	Dynamic fatigue test Pass	Dynamic fatigue test Pass	Not applicable	**Identical**
Sterilization	Steam autoclave	Steam autoclave	Not applicable	**Identical**

FEATURE	Subject Device Straumann® Variobase™ for Bridge/Bar Cylindrical Subject Submission	Predicate Device Straumann® Variobase™ Abutments for Bridge/Bar (K151157)	Reference Predicate Devices Straumann® Variobase™ Abutments (K120822, K142890) Straumann® Screws (K132844, K041295)	Equivalence Discussion
Mode of Action	Screw-retained or cement retained	Screw-retained or cement retained	Not applicable	**Identical**
Reusable	No	No	Not applicable	**Identical**

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**.**

The following testing has been conducted or substantial equivalence to tested predicate devices has been demonstrated:

- Dynamic fatigue testing conforming to FDA guidance and ISO 14801.
- Software validation conforming to the requirements of IEC 62304.
- Sterilization validation conforming to ISO 17665-1 and ISO/TS 17665-2 (K151157 Straumann Variobase for Bridge/Bar).
- Biocompatibility testing conforming to ISO-10993-1 (K120822 Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC)

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.