March 30, 2018

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

Re: K173379
Trade/Device Name: Straumann® Variobase® for Crown AS
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 2, 2018
Received: March 5, 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*
K173379

Device Name

Straumann® Variobase® for Crown AS

Indications for Use *(Describe)*

The Straumann® Variobase® for Crown AS is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for Crown AS are indicated for screw retained single tooth or cement-retained single tooth and bridge restorations. 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. All digitally designed copings and/or crowns for use with the Straumann Variobase® for Crown AS 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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K173379

510(k) Summary

1.1 Submitter's Contact Information

Submitter: Straumann USA, LLC (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810

Contact Person: Jennifer M. Jackson, MS
Director, Regulatory Affairs and Quality
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Prepared By: Dr. Gordon Dodds
Manager Design Control QM
Etkon GmbH

Date Prepared: March 26, 2018

Product Code(s): NHA (§872.3630)

Device Class: II (§872.3630)

Classification Panel: Dental

1.2 Name of the Device

Classification Name: Endosseous dental implant abutment (§872.3630)

Proprietary Name: Straumann® Variobase® for Crown AS

1.3 Predicate Device(s)

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

Reference Device(s):
- K120822 – Straumann CARES Variobase Abutment
- K170354 – Straumann Variobase Abutments
- K170356 – Straumann Variobase Abutments

1.4 Device Description

The Straumann® Variobase® for Crown AS are pre-manufactured (stock) lower parts of two-piece abutments, sometimes referred to as “bonding bases” or "TiBases". The Straumann® Variobase® for Crown AS are available to fit to Straumann® dental implant platforms NNC (Narrow Neck CrossFit®), RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit®), and RC (Regular CrossFit®).

There are two prosthetic heights to allow for treatment flexibility and for each of the bone level connections (NC, RC), there are gingiva heights of 1.00 mm, 2.00 mm and 3.00 mm. The Straumann® Variobase® for Crown AS provides the dental technician and patient with the possibility to have an “Angled Screw channel” in the crown.

The lower side of the Straumann® Variobase® for Crown AS and a small angulation of the inner-wall allows the screw-channel exit to move from a position directly above the implant screw channel to a laterally displaced position. Thus the screw-channel exit can be moved a small distance from occlusal contact or esthetic regions to regions where its potential impact to esthetics is smaller, in Figure 1 the screw-channel exit has been moved from the occlusal contact point of an incisor to behind the incisal edge. The patient-specific upper part of the two-piece abutment (referred to as coping or crown) is to be designed via a traditional workflow of casting/pressing or a digital workflow using the dental CAD software Straumann CARES Visual.

There are three components to the Straumann® Variobase® for Crown AS:

- Straumann® Variobase® for Crown AS (Ti-base)
- Prosthetic restoration (coping and/or crown)
- Basal Screw

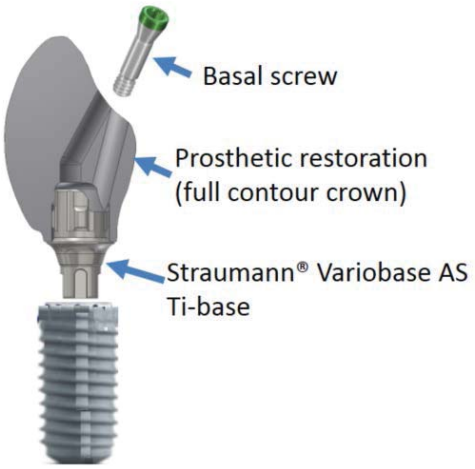

Figure 1 – Two-piece abutment consisting of a Straumann® Variobase® for Crown AS and a milled coping

The following is an overview of the possible prosthetic restoration (coping and/or crown) materials:

- Cast materials:
    - Type 4 metals (ISO 22674)
    - Base metal alloys (e.g., cobalt-chromium (CoCr))
    - Noble metal alloys (e.g., gold alloy)
- Press materials:
    - IPS e.max® Press Ceramic
- Digital materials:
    - coron®
    - zerion® LT
    - polycon® ae
    - zerion ML
    - zerion UTML
    - IPS e.max® CAD Ceramic
    - n!ce

1.5 Intended Use

Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations.

1.6 Indications for Use

The Straumann® Variobase® for Crown AS is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for Crown AS are indicated for screw retained single tooth or cement-retained single tooth and bridge restorations. 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. All digitally designed copings and/or crowns for use with the Straumann Variobase® for Crown AS are intended to be sent to Straumann for manufacture at a validated milling center.

1.7 Technological Characteristics

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

Table 1 – Device Substantial Equivalence Comparison – Straumann® Variobase® for Crown AS

Feature	SUBJECT Straumann® Variobase® for Crown AS	PREDICATE K142890, Straumann Variobase Abutments	REFERENCE K120822 Straumann CARES Variobase Abutment	Equivalence Discussion
Indications for Use	The Straumann® Variobase® for Crown AS is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for Crown AS are indicated for screw retained single tooth or cement-retained single tooth and bridge restorations. 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. All digitally designed copings and/or crowns for use with the Straumann® Variobase® for Crown AS are intended to be sent to Straumann for manufacture at a validated milling center.	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. 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.	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.	**Identical** Temporary materials crowns (Polycon AE) are used with the subject and predicate devices. The subject devices include advice to ensure that temporary restorations are placed out of occlusion in order to assist with implant stabilization. Updates to the predicate device IFUs, made since 510(k) clearance, give identical advice as the subject device.
TiBase Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	**Identical**

Feature	SUBJECT Straumann® Variobase® for Crown AS	PREDICATE K142890, Straumann Variobase Abutments	REFERENCE K120822 Straumann CARES Variobase Abutment	Equivalence Discussion
Abutment Diameter	3.8 mm – 7.0 mm	3.8 mm – 7.0 mm	3.8 mm – 7.0 mm	**Identical**
Prosthetic Height (Abutment Post Height)	3.5 mm – 6.5 mm	3.5 mm – 4.5 mm	3.5 mm – 4.5 mm	**Equivalent** The option for additional height of the apical part of the TiBase in Straumann® Variobase® for Crown AS provides for a larger area of retentive cement and material for resisting force.
Mode of Attachment	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	**Identical**
Basal Screws	TAN Basal screws for NC/RC, NNC, RN/WN interfaces with a wider screwhead (~10% wider) , to allow for up to 25° of angulation with respect to the Variobase AS axis with an angled screwdriver. Screws are marked with a green ring so they can be identified.	TAN Basal screws for NC/RC, NNC, RN/WN interfaces, with limited angled entry of screwdriver.	TAN Basal screws for NC/RC, NNC, RN/WN interfaces, with limited angled entry of screwdriver.	**Equivalent** A wider screw head permits the angulation. The cone below the screwhead is slightly longer to make the screw head wider. The screws have the same overall length,
Reusable	No	No	No	**Identical**
Source of Input Files for Crown Design	Intra-Oral Scanners Bench-top Scanners	Intra-Oral Scanners Bench-top scanners	Intra-Oral Scanners Bench-top scanners	**Identical**
Design Environment	Straumann CARES Visual: Closed CAD System facilitating the design of tooth-borne restorations and restorations used in conjunction with the devices of the Straumann Dental Implant System (SDIS).	Straumann CARES Visual: Closed CAD System facilitating the design of tooth-borne restorations and restorations used in conjunction with the devices of the Straumann Dental Implant System (SDIS).	Straumann CARES Visual: Closed CAD System facilitating the design of tooth-borne restorations and restorations used in conjunction with the devices of the Straumann Dental Implant System (SDIS).	**Identical**

Feature	SUBJECT Straumann® Variobase® for Crown AS	PREDICATE K142890, Straumann Variobase Abutments	REFERENCE K120822 Straumann CARES Variobase Abutment	Equivalence Discussion
Restoration Types Supported	Patient-specific copings and crowns for Variobase for Crown AS	Patient-specific copings and crowns for Variobase for Crown	Patient-specific copings and crowns for Variobase for Crown	**Equivalent**
Supported Restorative Materials	Traditional Workflow: Type 4 Metals (ISO 22674) IPS e.max® Press Ceramic Digital Workflow: IPS e.max® CAD Ceramic (permanent) coron® (permanent) zerion® (permanent) polycon® ae (temporary) zerion ML zerion UTML n!ce	Traditional Workflow: Type 4 Metals (ISO 22674) IPS e.max® Press Ceramic Digital Workflow: IPS e.max® CAD Ceramic (permanent) coron® (permanent)	Digital Workflow: polycon® ae (temporary) zerion® (permanent)	**Identical**
Fabrication Workflow	Traditional casting or pressing or Straumann Milling	Traditional casting or pressing or Straumann Milling	Straumann Milling	**Identical**
Reusable	No	No	No	**Identical**

1.8 Performance Testing

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:

- 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.

Variobase materials	Fatigue tests - predicates	Sterilization validation predicates	Biocompatibility testing – predicates
coron®	K142890	K142890	K142890
zerion® LT	Subject device	Subject device	K120822
polycon® ae	K142890	K120822	K142890
zerion ML/ zerion UTML	K170356	K170356	K170356
n!ce	K170354	K170354	K170354
IPS e.max CAD	K142890	K142890	K142890

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1.9 Conclusion

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.