DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 7, 2017

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

Re: K170354
Trade/Device Name: Straumann® Variobase® Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 8, 2017
Received: May 9, 2017

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.

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,

Lori A. Wiggins -S6

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)*

K170354

Device Name

Straumann® Variobase® Abutments

Indications for Use *(Describe)*

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.

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 K170354

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Date Prepared: June 01, 2017

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)

Common Name Endosseous dental implant abutment

Proprietary Name: Straumann® Variobase® Abutments

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

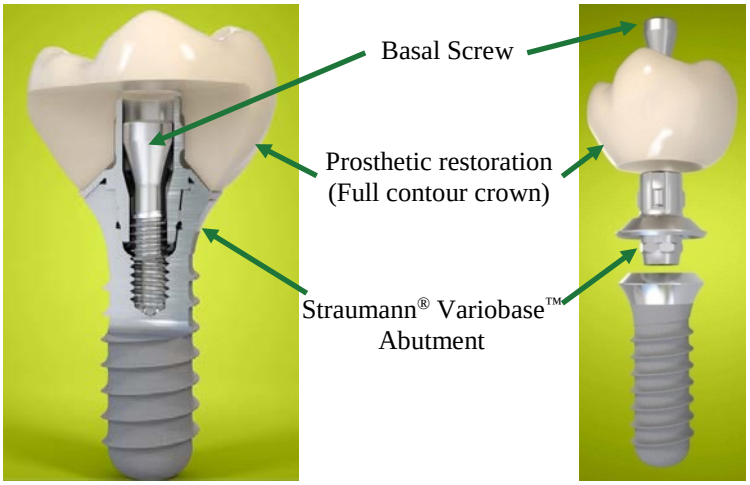
Reference Device(s): K160262, n!ce Glass Ceramic Blocks (Institut Straumann)
K120822, CARES Variobase Abutments (Institut Straumann)

Device Description: The purpose of the subject submission is to add the previously cleared Straumann n!ce glass ceramic material (K160262) as a cleared material suitable for fabrication of the coping or crown that, when bonded to the previously cleared Variobase abutment base (K142890), forms a finished dental prosthesis.

The Straumann Variobase Abutments are pre-manufactured (stock) abutments, sometimes referred to as "Ti-bases". Straumann Variobase Abutments are available to fit Straumann dental implant platforms NNC (Narrow Neck CrossFit®), RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit), and

RC (Regular CrossFit). A dental laboratory technician would design the corresponding coping and/or crown (the second component of the Variobase two-piece abutment) and/or prosthetic restoration in the dental laboratory via their preferred workflow. The coping and/or crown would be manufactured via traditional laboratory methods for pressing or casting, or via validated Straumann milling.

Picture of Device



Indications For Use:

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.

Materials:

- Straumann Variobase Abutments: Titanium-6 aluminum-7 niobium alloy (Ti-6Al-7Nb, TAN). The Ti-base components of the Straumann® Variobase™ Abutments are identical to the Ti-base components of the Straumann predicates (K142890).
- Straumann Basal Screw: Titanium-6 aluminum-7 niobium alloy (Ti-6Al-7Nb, TAN). The basal screw components of the Straumann® Variobase™ Abutments are identical to the basal screw components of the Straumann predicates (K142890).
- Coping or Crown: n!ce Glass Ceramic (lithium disilicate reinforced lithium aluminosilicate glass-ceramic). The material is identical to the material of the Straumann reference devices (K160262).

Technological Characteristics: A comparison of the relevant technological characteristics between the subject and primary predicate devices is provided in the table that follows.

Performance Data: The material used in the manufacture of Straumann Variobase Abutments is a titanium-aluminum-niobium alloy which meets the requirements of ISO 5832-11. Bench testing was performed to evaluate the performance of the proposed Straumann® Variobase™ Abutments.

- Dynamic fatigue tests were conducted in according to the FDA guidance document *"Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments"*.
- Steam sterilization validation per FDA guidance entitled *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* dated March 17, 2015 and the ISO 17665 series standards.
- Biocompatibility of the Straumann n!ce Glass Ceramic was established per K160262 based upon a cytotoxicity study per ISO 10993-5 and an inorganic extractables/leachables study per ISO 10993-18.
- Software validation per FDA guidance document: *General Principles of Software Validation; Final Guidance for Industry and FDA Staff,* issued on: January 11, 2002 and per IEC 62304.

No animal or human clinical studies were conducted.

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.

Feature	SUBJECT Devices Straumann Variobase Abutments	Primary PREDICATE Device Straumann Variobase Abutments (K142890)	Equivalence Discussion
Indications for Use	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.	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**
Ti-base Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	**Identical**
Abutment Diameter	3.8 – 7.0 mm	3.8 – 7.0 mm	**Identical**
Abutment Height	3.5 – 4.5 mm	3.5 – 4.5 mm	**Identical**
Max. Angulation	30°	30°	**Identical**
Coping/ Crown Material	Straumann n!ce Glass Ceramic is being added to the previously cleared coping/crown materials	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)	**Equivalent** The digital workflow is being expanded to add an additional material, Straumann n!ce glass ceramic. Straumann n!ce glass ceramic was shown to be substantially equivalent to IPS e.max CAD per K160262 cleared on September 16, 2016.
Design Workflow	Wax-up or CAD	Wax-up or CAD	**Identical**

Feature	SUBJECT Devices Straumann Variobase Abutments	Primary PREDICATE Device Straumann Variobase Abutments (K142890)	Equivalence Discussion
Manufacturing Workflow	Straumann Milling	Traditional casting or pressing or Straumann Milling	**Identical**
Mode of Attachment	Screw-retained or cement retained	Screw-retained or cement retained	**Identical**
Reusable	No	No	**Identical**