



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: K170356

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

Indications for Use

510(k) Number (if known)

K170356

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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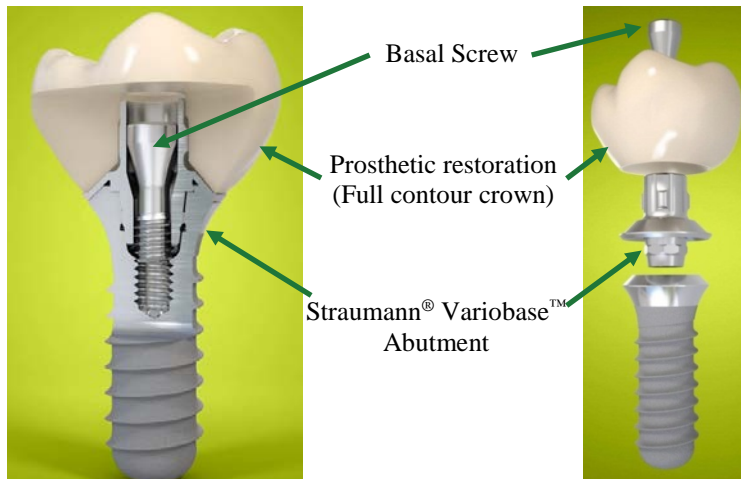
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- 5. 510(k) Summary **K170356****
- Submitter:** Straumann USA, LLC (on behalf of Institut Straumann AG)
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- Contact Person:** Jennifer M. Jackson, MS
Director of Regulatory Affairs and Quality
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- Prepared By &
Secondary Contact:** Christopher Klaczyk
Head of Regulatory Affairs & Compliance
Institut Straumann AG
+41 61 965 1260
- 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):** K050160, Katana Zirconia (Noritake Company)
K131534, KATANA Zirconia (Kuraray Noritake Dental)
K143439, KATANA Zirconia (Kuraray Noritake Dental)
K120822, CARES Variobase Abutments (Institut Straumann)
K151324, Variobase for CEREC (Institut Straumann)
- Device Description:** The purpose of the subject submission is to add the zerion® ML and zerion® UTML Zirconia ceramic materials as a material suitable for fabrication of the coping, crown or bridge that, when bonded to the previously cleared Variobase abutment base (K120822, 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 restoration will be manufactured 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 Straumann® Variobase™ Abutments are identical to 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, Crown or Bridge: zeron® ML Zirconia and zeron® UTML Zirconia ceramic materials.

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:	<p>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.</p> <ul style="list-style-type: none">• Dynamic fatigue tests were conducted in accordance to the FDA guidance document “<i>Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments</i>”.• Steam sterilization validation per FDA guidance entitled <i>Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling</i> dated March 17, 2015 and the ISO 17665 series standards.• Cytotoxicity per ISO 10993-5• Inorganic extractables/leachables per ISO 10993-18• Software validation per FDA guidance document: <i>General Principles of Software Validation; Final Guidance for Industry and FDA Staff</i>, issued on: January 11, 2002 and per IEC 62304. <p>No animal or human clinical studies were conducted.</p>
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	zerion® ML zirconia ceramic and zerion® UTML zirconia ceramic are being added to the previously cleared coping/crown materials	<u>Traditional Workflow:</u> Type 4 Metals (ISO 22674) IPS e.max® Press Ceramic <u>Digital Workflow:</u> polycon® ae (temporary) zerion® (permanent) IPS e.max® CAD Ceramic (permanent) coron® (permanent)	Equivalent The digital workflow is being expanded to add additional materials, zerion® ML & UTML zirconia ceramics. zerion® ML & UTML zirconia ceramics are substantially equivalent to the previously cleared zerion® HT zirconia ceramics
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