October 5, 2018

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

Re: K173945
Trade/Device Name: Straumann® SC Variobase® Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 17, 2018
Received: September 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173945

Device Name
Straumann® SC Variobase® Abutments

Indications for Use *(Describe)*
Straumann® SC Variobase® abutments are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration can be cemented on the Straumann® SC 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. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated.
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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K173945 510(k) Summary

Submitter's Contact Information

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

Phone Number: 1-978-747-2509

Fax Number: 1-978-747-0023

Contact Person: Jennifer M. Jackson, MS

Date Prepare: October 4, 2018

Name of the Device

Trade Names: Straumann® SC Variobase® Abutments

Common Name: Endosseous Dental Implant Abutment

Classification Name: Endosseous Dental Implant Abutment

Regulation Number: §872.3630

Classification: Class II

Product Codes: NHA

Predicate Device(s)

Primary Predicate:

K162890 – Straumann® Ø2.9 mm Bone Level Tapered Implant

Reference Devices:

K170356 – Straumann® Variobase® Abutments

Device Description

There are three components to the Straumann® SC Variobase® Abutments:

- Straumann® SC Variobase® Abutments (Ti-base)
- Prosthetic restoration (coping and/or crown)

- Basal Screw

The Straumann® SC Variobase® Abutments are manufactured from TAN. The abutments are oval in shape to accommodate narrow interdental spaces and are available with three different gingival heights ranging between 1.0 mm and 3.0 mm. The abutments will be delivered with the corresponding basal screw.

The prosthetic restoration (the second component of the two-piece abutment) is digitally designed using CAD software and sent to Straumann for manufacture at a validated milling center.

The purpose of this submission is to add the following materials to the previously cleared list of top-half materials for use on the previously cleared Straumann® SC Variobase® Abutments:

- Digital materials:
    - zerion ML
    - zerion UTML

The following design parameters must be followed when designing the prosthetic restoration in CAD Software:

	zerion ML	**zerion UTML**
Minimum Wall Thickness	0.4 mm	0.8 mm
Minimum Angulation	0˚	0˚
Maximum Angulation	30˚	30˚

Intended Use

Straumann® SC Variobase® Abutments are intended to be placed into Straumann® Bone Level Tapered Implants ø2.9 mm to provide support for individual crowns or bridges.

Indications for Use

Straumann® SC Variobase® abutments are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration can be cemented on the Straumann® SC 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. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated.

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.

Technological Characteristics

The technological principles and intended use are identical for the subject and reference predicate devices. The devices are intended to be placed into dental implants to provide support for individual crowns or bridges. The main difference in the technological characteristics between the subject and primary predicate devices is the coping/crown materials. The coping/crown material is identical to the reference predicate device. The technological characteristics of the subject devices are compared to the primary and reference predicates in Table 1.

Traditional 510(k) Submission

Straumann® SC Variobase® Abutments

510(k) Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
K Number	**Subject Device**	**K162890**	**K170356**
Material	Ti-6Al-7Nb	Ti-6Al-7Nb	Ti-6Al-7Nb
Indications for Use Statement	Straumann® SC Variobase® abutments are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration can be cemented on the Straumann® SC 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. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated. 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.	Straumann® SC Variobase® abutments are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration can be cemented on the Straumann® SC 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. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated. 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. 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.
Implant to Abutment Connection	Small CrossFit® (SC)	Small CrossFit® (SC)	Narrow CrossFit® (NC) Regular CrossFit® (RC) Narrow Neck CrossFit® (NNC) Regular Neck (RN) Wide Neck (WN)
Diameter or Minor Oval Dimension/ Major Oval Dimension	3.3/4.3 mm	3.3/4.3 mm	Ø3.8 – 7.0 mm
Overall Abutment Height	6.7 – 8.7 mm	6.7 – 8.7 mm	5.9 – 8.9 mm
Coping/ Crown Material	Digital Workflow: zerion ML (permanent) zerion UTML (permanent)	Traditional Workflow: Type 4 metals (ISO 22674) IPS e.max® Press Ceramic Digital Workflow: coron® (permanent) zerion® LT (permanent) polycon® ae (temporary)	Digital Workflow: zerion ML (permanent) zerion UTML (permanent)

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
K Number	**Subject Device**	**K162890**	**K170356**
Design Workflow	Wax-up or Open CAD	Wax-up or Open CAD	Wax-up or Open CAD CARES® Visual
Design Parameters – Minimum Wall Thickness	zerion ML – 0.4 mm zerion UTML – 0.8 mm	zerion® LT – 0.4 mm coron® – 0.3 mm polycon® ae – 0.5 mm	zerion ML – 0.4 mm zerion UTML – 0.8 mm
Design parameters – Minimum Angulation	0˚	0˚	0˚
Design Parameters – Maximum Angulation	30˚	30˚	30˚
Manufacturing Workflow	Straumann Milling	Traditional casting or pressing or Straumann Milling	Straumann Milling
Mode of Action	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained

Table 1 – Comparison of subject device versus reference device (Straumann® SC Variobase® Abutments)

Performance Testing

The following performance data were provided in support of the substantial equivalence determination.

Sterilization Validation

The sterilization process for the Straumann® SC Variobase® Abutments as recommended in the labeling was validated according to applicable recommendations in the FDA guidance document "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015"*.

The subject devices have the identical sterilization methods compared to the primary and reference predicate devices. No new issues regarding sterilization were raised for the subject devices. Therefore, no additional sterilization validations were required.

Biocompatibility Testing

The subject devices were evaluated according to ISO 10993-1:2009 *"Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" and the biocompatibility evaluation flow chart according to the FDA Guidance document *"Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff, Document issued on: June 16, 2016"* for the subject devices.

The subject devices have the identical nature of body contact, contact duration, material formulation, manufacturing processes, and sterilization methods compared to the primary and reference predicate devices. No new issues of biocompatibility are raised for the subject devices. Therefore, no additional biocompatibility testing was required.

Bench Testing

Dynamic fatigue and static strength tests were conducted 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*" and demonstrated the Straumann® SC Variobase® Abutments are equivalent to the primary predicate devices.

Conclusion

The documentation submitted in this premarket notification demonstrates the Straumann® SC Variobase® Abutments are substantially equivalent to the primary predicate and reference devices.