October 28, 2019

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

Re: K192029
Trade/Device Name: Straumann® PUREloc abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 29, 2019
Received: July 30, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*

K192029

Device Name:

Straumann® PUREloc abutments

Indications for Use *(Describe)*

The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann implants.

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

Traditional 510(k) Submission

Straumann® PUREloc Abutments

5 510(k) Summary

5.1 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 M. Jackson, MS Director of Regulatory Affairs and Quality Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023 email: jennifer.jackson@straumann.com
Prepared By & Alternate Contact:	Giulia Oran Regulatory Affairs and Compliance Manager Institut Straumann AG Phone number : +41 61 965 16 17
Date of Submission:	October 28, 2019

5.2 Name of the Device

Trade Names:	Straumann® PUREloc abutments
Common Name:	Endosseous dental implant abutment
Classification Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630
Device Classification :	II
Product Code(s):	NHA
Classification Panel:	Dental
Proprietary Name:	Straumann® PUREloc Abutments

5.3 Predicate Device(s)

Primary Predicate:

- K190040 – Straumann BLX Line Extension – New Abutments

Traditional 510(k) Submission

Straumann® PUREloc Abutments

Reference Devices:

- K180477 – Straumann PURE Ceramic Implant
- K190662 – MRI compatibility for existing Straumann dental implant systems

5.4 Device Description

The Straumann® Retentive System (to which PUREloc belongs) is designed for the use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla. The Straumann® Retentive System consists of abutments which are used for the restoration of Straumann dental implants of different types, endosteal diameters, lengths and platforms. They are available in different sizes and angles to fit individual patient needs. Straumann® PUREloc abutments are used exclusively on the Straumann PURE Ceramic Implants, are available in 6 heights (1 mm, 2 mm, 3 mm, 4 mm, 5 mm, and 6 mm) and made of Yttrium-stabilized zirconia ceramic (ISO 13356 - Implants for surgery — Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)). The Straumann® PUREloc abutments are non-engaging and the implant-to-abutment connection is provided for by the basal screw. The basal screw is manufactured from Titanium Grade 4 and is identical to the basal screw cleared under K180477.

5.5 Intended Use

Prosthetic components connected to the implant or abutment, are intended for use as an aid in prosthetic rehabilitation.

5.6 Indications for Use

The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann implants.

5.7 Technological Characteristics

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

Traditional 510(k) Submission

Straumann® PUREloc Abutments

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
K Number	K192029	K190040	K180477	K190662
Indications for Use	The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants.	**Straumann BLX Healing Abutments for Bars and Bridges** Straumann Healing abutments are indicated to be placed in the patient's mouth at the end of the implant placement to protect the inner configuration of the implant and to form, maintain and stabilize the soft tissue during the healing process. Healing abutments should be used only with suitable implant connections. Healing components have a maximum duration of usage of 6 months. **Straumann BLX Temporary Abutments for Bar and Bridges** Prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Temporary components can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they may not be placed into occlusion. Final abutments may be placed into occlusion when the implant is fully osseointegrated. BLX Temporary Abutments have a maximum duration of usage of 180 days. **Straumann BLX Variobase Abutments for Bar and Bridges** Straumann® Variobase™ prosthetic components directly or indirectly connected to the endosseous dental	**Straumann PURE Ceramic Implant:** The Straumann PURE Ceramic Implant is indicated for the restoration of single-tooth gaps and in edentulous or partially edentulous jaws. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components. **Closure and healing caps**: Closure and Healing caps are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Closure and Healing caps should be used only with suitable implant connections. Do not use healing components for longer than 6 months. **Temporary Abutments**: The provisional components are intended to serve as a base for temporary crown or bridge restoration out of occlusion for the Straumann® PURE Ceramic Implant System. The Straumann® Temporary Abutment VITA CAD-Temp® for the Straumann® PURE Ceramic Implant is indicated for temporary usage of up to 180 days. **CI RD Straumann PUREbase Abutments**: CI RD Straumann PUREbase abutment is a titanium base placed	n/a

Traditional 510(k) Submission

Straumann® PUREloc Abutments

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
K Number	K192029	K190040	K180477	K190662
		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. **Straumann BLX Variobase Abutments AS** 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. **Straumann BLX Novaloc Abutments**	onto Straumann ceramic dental implants to provide support for customized prosthetic restorations and is 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.	

Traditional 510(k) Submission

Straumann® PUREloc Abutments

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
K Number	K192029	K190040	K180477	K190662
		The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants. **Straumann BLX CARES Abutments** The Straumann CARES Abutments are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw-retained.		
Material	Y-TZP according to ISO 13356	Ti-6Al-4V	Y-TZP according to ISO 13356	n/a
Surface Treatment	none	Partially anodized / TiN coated	Sand-blasted, large-grit, acid etched (ZLA®)	n/a
Implant to Abutment Connection	Screw-retained (via CI Basal Screw)	TorcFit connection	Screw-retained (via CI Basal Screw)	n/a
Diameter	4.8 mm	4.5 mm	4.1 mm (endosteal ∅) 4.8 mm (platform ∅)	n/a
Gingival height	1, 2, 3, 4, 5, 6 mm	1.5 to 6.5 mm	n/a	n/a
Abutment-to-restoration connection	Snap on feature	Snap on feature	n/a	n/a
Type of recommended restoration	Multi-unit	Multi-unit	n/a	n/a
Abutment Angulation	straight	0 and 15°	n/a	n/a
Sterilization Method	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized	Ethylene Oxide	

Traditional 510(k) Submission

Straumann® PUREloc Abutments

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
K Number	K192029	K190040	K180477	K190662
MRI Compatibility	MRI conditional	Labeling does not contain MRI Safety Information	Labeling does not contain MRI Safety Information	MRI conditional

Table 1 – Comparison of subject device versus primary predicate device and reference predicate device

The primary predicate (K190040) is included for reference to the Straumann BLX Novaloc Abutments. The indications for use for the primary predicate contains reference to many different types of abutments. The intended use and indications for use of the subject device are identical to the Straumann BLX Novaloc Abutments. Dimensionally, the platform diameter is slightly smaller for the subject device to accommodate the implant diameter of the compatible implants. The material of the subject device is identical to the implants of the reference device (K180477) and the screw used to secure the abutment to the implant is identical to the basal screw cleared under K180477.

The reference device (K190662) is included in support of considerations for MRI compatibility.

5.8 Performance Testing

5.8.1 Sterilization

The sterilization process for the PUREloc 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*".

5.8.2 Biocompatibility

The subject device materials were evaluated for biocompatibility 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".

Although the subject devices materials are identical to the primary predicate and reference devices, cytotoxicity and chemical characterization tests were performed due to differences in geometry, manufacturing processes, and sterilization processes to confirm biocompatibility. These tests were conducted according to ISO 10993-5, 10993-12, and 10993-18 and confirmed the subject devices are biocompatible.

5.8.3 Bench testing

Dynamic fatigue was 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"*, furthermore snapping force, and dynamic force tests were performed and demonstrated that the PUREloc abutments are identical to primary predicate (K190040) in terms of performance.

5.9 Conclusion

The documentation submitted in this premarket notification demonstrates the PUREloc abutments are substantially equivalent to the primary predicate and reference devices.