February 12, 2021

Institut Straumann AG
% Jennifer Jackson
Director, Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01801

Re: K203355
Trade/Device Name: Straumann TLX Novaloc and Cementable Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 12, 2020
Received: November 16, 2020

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,

Andrew Steen
Assistant 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)*

K203355

Device Name:

Straumann TLX Novaloc and Cementable Abutments

Indications for Use *(Describe)*

TLX Novaloc Abutments

The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants (NT, RT, and WT).

TLX Cementable Abutments

Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Final abutments may be placed into occlusion for implants with sufficient primary stability and with appropriate occlusal loading to restore chewing function or for implants that are fully osseointegrated.

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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5 510(k) Summary

5.1 Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052
	On the behalf of: Institut Straumann AG Peter Merian-Weg 12 4052 Basel, Switzerland
Contact Person:	Jennifer M. Jackson, MS Director of Regulatory Affairs Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023
Prepared By & Alternate Contact:	Laure Kuhner Regulatory Affairs Specialist Institut Straumann AG Phone Number: +41 61 965 1389
Date of Submission:	February 4, 2021

5.2 Name of the Device

Trade Names:	Straumann TLX Novaloc and Cementable Abutments
Common Name:	Endosseous Dental Implant Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Device Classification:	Class II
Product Code(s):	NHA
Classification Panel:	Dental devices
Proprietary Name:	Straumann TLX Novaloc and Cementable Abutments

5.3 Predicate Device(s)

Primary Predicate:

- K193046 - Straumann® Retentive System – Novaloc TiN Abutments

Reference Devices:

- K113283 - Narrow Neck CrossFit (NNC) Cementable Abutments
- K200586 - Straumann TLX Implant System
- K190662 - MRI Compatibility for Existing Straumann Dental Implant Systems

5.4 Device Description

Straumann TLX Novaloc Abutments

The subject TLX Novaloc Abutments are intended to be placed onto Straumann TLX implants to provide support for full arch detachable restorations (over-denture). The coronal portion of the subject abutments is similar to the primary predicate devices, whereas the apical portion of the abutments has the appropriate implant-to-abutment interface geometry for each of the platforms of the Straumann TLX Implant System (NT, RT and WT). The Novaloc Abutments are manufactured from TAV (Ti-6Al-4V, Titanium-Aluminum-Vanadium). The restoration is connected to the Novaloc Abutment through a snap-on fixture provided by a negative shape of Novaloc snap-on fixture embedded into the final restoration. The snap-on feature is TiN coated. The subject TLX Novaloc Abutments are provided in straight and angulated versions, in different heights. The TLX Novaloc Abutments are provided non-sterile with instructions for end user sterilization.

Straumann TLX Cementable Abutments

The subject TLX Cementable Abutments are intended to provide support for prosthetic reconstructions such as crowns and bridges and are used with cemented restorations. They are made of titanium alloy (Ti-6Al-7Nb or TAN) and are attached to the implant with a basal screw. To allow for more flexibility they are offered in a straight and in an angulated version for each of the three platforms (NT, RT and WT). The TLX Cementable Abutments are provided non-sterile with instructions for end user sterilization.

5.5 Indications for Use

Straumann TLX Novaloc Abutments

The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants (NT, RT, and WT).

Straumann TLX Cementable Abutments

Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Final abutments may be placed into occlusion for implants with sufficient primary stability and with appropriate occlusal loading to restore chewing function or for implants that are fully osseointegrated.

5.6 Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in Table 1 and Table 2.

K203355 – Traditional 510(k)

Straumann TLX Novaloc and Cementable Abutments

510(k) Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE
K Number	K203355	K193046 Straumann® Retentive System – Novaloc TiN Abutments	K200586 Straumann TLX Implant System (TLX Variobase for Crown)
Indications for Use	The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants (NT, RT, and WT).	The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants.	Straumann® Variobase® prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. The prosthetic restoration (crowns) can be cemented onto the Straumann® Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they must be placed out of occlusion. 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.
Material	TAV (Ti-6Al-4V)	TAV (Ti-6Al-4V)	TAN (Ti-6Al-7Nb)
Surface Treatment	Coronal portion: TiN coating Apical portion: Laser marking	Coronal portion: TiN coating Apical portion: Laser marking	Laser marking
Implant to Abutment Connection	TorcFit	CrossFit and synOcta	TorcFit
Prosthetic platform	NT, RT and WT	NC, RC, RN and WN	NT, RT and WT
Gingival Height	Straight: 1, 2, 3, 4, 5, and 6 mm Angled: 2, 3, 4, 5, and 6 mm	Straight: 1, 2, 3, 4, 5, and 6 mm Angled: 2, 3, 4, 5, and 6 mm	5.5 mm, 6 mm and 6,5 mm
Angulation	0° and 15°	0° and 15°	0°
Sterilization method	Moist heat end user sterilization	Moist heat end user sterilization	Moist heat end user sterilization

Table 1 – Comparison of subject TLX Novaloc Abutments versus primary predicate and reference devices

K203355 – Traditional 510(k)

Straumann TLX Novaloc and Cementable Abutments

510(k) Summary

FEATURE	PROPOSED DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	K203355	K113283 Narrow Neck CrossFit (NNC) Cementable Abutments	K200586 Straumann TLX Implant System
Indications for Use	Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Final abutments may be placed into occlusion for implants with sufficient primary stability and with appropriate occlusal loading to restore chewing function or for implants that are fully osseointegrated.	Abutments are used in connection with the prosthetic restoration of Straumann dental implants. Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges. Narrow Neck CrossFit Cementable Abutments are indicated for cement-retained single tooth and bridge restorations.	TLX Dental Implant: Straumann TLX Implants are suitable for endosteal implantation in the upper and lower jaws and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. TLX Implants can be placed with immediate function on single-tooth and multi-unit restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding abutment components. TLX Variobase for Crown: Straumann Variobase prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. The prosthetic restoration (crowns) can be cemented onto the Straumann Variobase prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they must be placed out of occlusion. 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.
Material	TAN (Ti-6Al-7Nb)	Titanium, Grade 4	TAN (Ti-6Al-7Nb)
Surface Treatment	Laser marking	Laser marking	Laser marking
Implant to Abutment Connection	TorcFit	CrossFit	TorcFit
Prosthetic platform	NT, RT and WT	NNC	NT, RT and WT

FEATURE	PROPOSED DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	K203355	K113283 Narrow Neck CrossFit (NNC) Cementable Abutments	K200586 Straumann TLX Implant System
Chimney height	Straight: 5,7 mm and 6 mm Angled: 6 mm	Straight: 5,7 mm Angled: 5,9 mm	5.5 mm, 6 mm and 6,5 mm
Angulation	0° and 15°	0° and 15°	0°
Sterilization method	Moist heat end user sterilization	Moist heat end user sterilization	Moist heat end user sterilization

Table 2 – Comparison of subject TLX Cementable Abutments versus reference devices

5.7 Performance Testing

5.7.1 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 ISO 14801, "*Dentistry – Implants – Dynamic fatigue test for endosseous dental implants"* and demonstrated that the Straumann TLX Novaloc and Cementable Abutments are equivalent to the primary predicate and reference devices.

5.7.2 Biocompatibility Testing

Biological assessment has been performed according to ISO 10993-1:2009 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" and 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 each of the subject devices.

The subject devices have equivalent nature of body contact, contact duration, material formulation and sterilization methods compared to the primary predicate and reference devices, therefore, no new issues regarding biocompatibility were raised.

5.7.3 Sterilization Validation

The subject Straumann TLX Novaloc and Cementable Abutments are provided non-sterile and need to be sterilized by moist heat (steam) by the end-user. The recommended sterilization method has been validated according to ISO 17665-1 and ISO 17665-2 and to applicable recommendations in the FDA guidance document "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015*". There are no changes to the sterilization procedures or processes from those of the primary predicate and reference devices.

5.8 Conclusion

The documentation submitted in this premarket notification demonstrates the Straumann TLX Novaloc and Cementable Abutments are substantially equivalent to the primary predicate and reference devices.