August 13, 2020

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

Re: K193046
Trade/Device Name: Straumann® Retentive System - Novaloc TiN Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 16, 2020
Received: July 17, 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,

for Srinivas Nandkumar, Ph.D.
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)*

K193046

Device Name:

Straumann® Retentive System – Novaloc TiN Abutments

Indications for Use *(Describe)*

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

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 and Quality Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023
Prepared By & Alternate Contact:	Ana Carolina Martins Vianna Regulatory Affairs and Compliance Manager Institut Straumann AG Phone Number: +41 61 965 1259
Date of Submission:	August 11, 2020

5.2 Name of the Device

Trade Names:	Straumann® Retentive System – Novaloc TiN 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

5.3 Predicate Device(s)

Primary Predicate:

- K190040 - Straumann BLX Line Extension - New Abutments

Reference Devices:

- K033699 – Locator Bar Female
- K151157 – Straumann Variobase Abutments For Bridges/Bars
- K171649 – Straumann CARES M-Series CAD/CAM System
- K190662 – MRI Compatibility for Existing Straumann Dental Implant Systems

5.4 Device Description

The subject Novaloc TiN Abutments are intended to be placed onto Straumann dental implants to provide support for full or partial arch detachable restorations (over-denture). The coronal portion of the subject abutments are 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 Dental Implant System. 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 Novaloc TiN Abutments are provided in straight and angulated models, in different heights. The subject Novaloc TiN Abutment is also provided in a bar attachment. The Novaloc TiN abutments are provided non-sterile with instructions for end user sterilization.

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 dental implants and bar constructs.

5.7 Technological Characteristics

The primary predicate devices and subject devices have many of the same technological characteristics. The abutment material, surface coating, angulation and snap-on feature are identical to the primary predicate device. The main technological difference is the implant-to-abutment connections. Nevertheless, all subject connections are well established and compatible with FDA cleared Straumann implant connections (NC, RC, RN, and WN). A complete comparison of the primary and reference predicate devices with the subject abutments is provided in Table 1.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICES	
K Number	**K193046**	**K190040**	**K171649**	**K151157**
Indications for Use	The Straumann Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants and bar constructs.	**Straumann BLX Novaloc Abutments**: The Straumann Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants. (Indications for Use related to other types of abutments are not considered in this table)	The Straumann CARES M-Series CAD/CAM System is indicated for the design and fabrication of single or multiple- unit implant-borne prosthetics for the restoration of partially or fully edentulous mandibles and maxillae. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners or Extra-Oral Scanners, CAD software, CAM software, restoration material blanks, milling machines and associated tooling and accessories. The system is used to design and fabricate CAD/CAM milled coping, crown and bridge restorations to be cemented onto Straumann® Variobase® Abutments, as well as milled abutments to be affixed to the endosseous dental implants of the Straumann® Dental Implant System using a basal screw.	Straumann Variobase prosthetic components directly connected to the endosseous dental implants are indicated 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.
Material	TAV (Ti-6Al-4V)	TAV (Ti-6Al-4V)	Ti-6Al-7Nb	Ti-6Al-7Nb
Surface Treatment	TiN coating	TiN coating	No coating	No coating

K193046 – Traditional 510(k)

Straumann Retentive System – Novaloc TiN Abutments

510(k) Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICES	
K Number	**K193046**	**K190040**	**K171649**	**K151157**
Implant to Abutment Connection	Straumann NC connection Straumann RC connection Straumann RN connection Straumann WN connection	Straumann BLX connection	Straumann NC connection Straumann RC connection Straumann NNC connection Straumann RN connection Straumann WN connection	Straumann NC connection Straumann RC connection Straumann NNC connection Straumann RN connection Straumann WN connection
Abutment Height	1, 2, 3, 4, 5, and 6 mm	up to 6.5 mm	n/a	3.5 – 5.2 mm
Angulation	0 and 15°	0 and 15°	30° of coping angulation	30° of coping angulation
Sterilization Method	Moist heat end user sterilization	Moist heat end user sterilization	Moist heat end user sterilization	Moist heat end user sterilization

Table 1 – Comparison of subject Novaloc TiN Abutments versus primary predicate and reference 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.

The reference device K190662 is included for the MRI compatibility.

The subject Novaloc Abutments for bar attachments are equivalent to the reference device K033699 as described in Table 2.

FEATURE	PROPOSED DEVICE	REFERENCE DEVICE
K Number	**K193046**	**K033699**
Indications for Use	The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants and bar constructs.	The Locator Bar Attachment System is designed for use with overdentures or partial dentures retained in whole or in part by bar splinted endosseous implants in the mandible or maxilla
Connection	Bar	Bar
Abutment to restoration connection	Snap on feature	Snap on Feature
Type of restoration	Multiunit	Multiunit
Compatible Matrix System	Zest LOCATOR Valoc Novaloc	Zest LOCATOR
Angulation	0˚	0˚

Material	Titanium grade 5 alloy (Ti-6Al-7V or TAV)	Titanium, Stainless Steel
Abutment Coating	TiN	TiN
Construction	One Piece	One Piece
Sterility	Non-sterile End user sterilization	Non-sterile End user sterilization

Table 2 – Comparison of subject Novaloc Abutments for bar attachments versus reference device

5.8 Performance Testing

The following performance data support the substantial equivalence determination.

5.8.1 Sterilization Validation

The subject Novaloc TiN 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 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 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 the same nature of body contact, contact duration, material formulation and sterilization methods compared to the primary predicate devices.

5.8.3 Bench Testing

Dynamic fatigue and static strength tests 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, demonstrated that the Straumann Novaloc TiN Abutments are equivalent to the predicate and reference devices.

5.8.4 Clinical data

No device specific clinical data has been submitted to demonstrate substantial equivalence.

5.9 Conclusion

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