December 28, 2018

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

Re: K181703
Trade/Device Name: Straumann® BLX Line Extension - Implants, SRAs and Anatomic Abutments
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 27, 2018
Received: November 28, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181703

Device Name
Straumann® BLX Line Extension - Implants, SRAs and Anatomic Abutments

Indications for Use *(Describe)*

Straumann® BLX Implants
Straumann® BLX Implants are suitable for endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. BLX Implants can be placed with immediate function on single-tooth, bar and bridge applications 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.

Straumann® BLX SRAs and Antomic Abutments
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.

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.

510(k) Summary

Submitter's Contact Information

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

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Contact Person: Jennifer M. Jackson, MS

Prepared by: Ana Carolina Martins Vianna
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Date of Submission: December 28, 2018

Name of the Device

Trade Names: Straumann® BLX Line Extension – Implants, SRAs and Anatomic Abutments

Common Name: Endosseous Dental Implant

Classification Name: Endosseous Dental Implant

Regulation Number: 21 CFR 872.3640
21 CFR 872.3630

Classification: Class II

Product Codes: Primary product code DZE
Secondary product code NHA

Predicate Device(s)

Primary Predicate:

- K173961 – BLX Implant System

Reference Devices:

- K071357 – P.004 NC Anatomic Abutments

- K133421 – Straumann Magellan Abutment, Protective Cap, Titanium Copings, Gold Copings, Basal Screw
- K171757 – Straumann Screw Retained Abutments
- K163194 – Neodent Implant System - GM Line

Indications for Use

Straumann® BLX Implants

Straumann® BLX Implants are suitable for endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. BLX Implants can be placed with immediate function on single-tooth, bar and bridges applications 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.

Straumann® BLX SRAs and Anatomic Abutments

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.

4.1 Device Description

The Straumann BLX Implants are fully tapered implants manufactured utilizing the Roxolid material and are finished with SLActive® surface. The connection is identified as conical fitting with Torx style engaging feature. There are two available prosthetic platforms identified as RB (Regular Base) and WB (Wide Base).

The subject devices have a RB platform (a “small top/head”) with a Torx-style internal connection, which is identical for all the implant lengths. They are provided sterile by gamma radiation and are available in the following sizes:

Platform	Neck Ø (mm)	Maximium outer Ø (mm)	Length (mm)
RB	3.5	3.75	8
			10
			12
			14
			16
			18

Straumann® BLX SRAs are manufactured from TAN and are intended to be placed on BLX Straumann dental implants to provide support for permanent screw-retained single or multi-unit restorations. They are provided sterile by gamma radiation and are available in the following sizes:

Platform	Ø (mm)	Angulation	Gingival heights (mm)
RB/WB	4.6	0°	1.5
			2.5
			3.5
			4.5
		17°	2.5
			3.5
			4.5
		30°	2.5
			3.5
			4.5

The angled versions are composed of the body of the abutment with a coupled basal screw whereas in the straight version both parts are machined in one piece.

The SRAs are provided with a transfer piece (Pin).

Straumann® BLX Anatomic Abutments are manufactured from TAN and are intended to be placed on BLX Straumann dental implants to provide support for permanent cement-retained single or multi-unit restorations. They are provided non-sterile and are available in the following sizes:

Platform	Angulation	Gingival heights (mm)
RB/WB	0°	2.5
		3.5
	17°	2.5
		3.5

They are delivered with the corresponding basal screw.

Anatomic Abutments are provided with pre-defined mucosa margins and with a size that allows for further modification by the customer via hand grinding tools.

Technological Characteristics

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

K181703 – 510(k) Summary

Straumann® BLX Line Extension – Implants, SRAs, and Anatomic Abutments

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	EQUIVALENCE DISCUSSION
	Subject Device – BLX Implants	**K173961** **Straumann BLX Implant System**	**K163194** **Neodent GM Line**	
Indications for Use	Straumann® BLX Implants are suitable for endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. BLX Implants can be placed with immediate function on single-tooth, bar and bridge applications 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.	Straumann® BLX Implants are suitable for endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. BLX Implants can be placed with immediate function on single-tooth applications 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.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	Equivalent All indications allows for implant placement in jaw, providing support for single-tooth, bar and bridge restorations, and allowing for immediate loading when good primary stability is achieved.
Material	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	Titanium grade 4	Identical Identical to the primary predicate device.
Surface Treatment	Hydrophilic SLActive®	Hydrophilic SLActive®	Acqua	Identical Identical to the primary predicate device.
Implant to Abutment Connection	BLX (with conical fitting)	BLX (with conical fitting)	GM interface (with conical fitting)	Equivalent All connections have conical fitting.
Implant Diameter	Ø 3.75 mm	Ø 4.5, 5.5, 6.5 mm	Ø 3.5 to 5.0 mm	Equivalent Into the range of diameters of the primary predicate and the reference devices.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	EQUIVALENCE DISCUSSION
	Subject Device – BLX Implants	**K173961** **Straumann BLX Implant System**	**K163194** **Neodent GM Line**	
Implant Length	8 to 18 mm	6 to 18 mm	8 to 18 mm	Equivalent Into the range of the predicate device and identical to the reference device.
Implant Body	Tapered body	Tapered body	Tapered and cylindrical bodies	Equivalent Into the range of body shapes of the primary predicate and the reference devices.
Thread Pitch	1.7 to 2.6	2.0 to 2.8 mm	Not available.	Equivalent The performance of the different thread pitches are assessed via insertion torque test.
Sterilization Method	Irradiation	Irradiation	Irradiation	Identical.

Table 1 – Comparison matrix: subject device versus primary and reference predicate devices (BLX Implants)

K181703 – 510(k) Summary

Straumann® BLX Line Extension – Implants, SRAs, and Anatomic Abutments

FEATURE	PROPOSED DEVICE	REFERENCE PREDICATE DEVICE		EQUIVALENCE DISCUSSION
	Subject Device - BLX SRAs	**K133421 (Straumann Magellan SRAs)**	**K171757 Straumann Screw Retained Abutments**	
Material	Ti-6Al-7Nb	Ti-6Al-7Nb	Ti-6Al-7Nb	Identical
Implant to Abutment Connection	BLX (with conical fitting)	CrossFit® (NC and RC) (with conical fitting)	CrossFit® (NC and RC) (with conical fitting)	Equivalent The subject devices have a conical implant-to-abutment fitting as well as the reference devices, nevertheless, each implant system has its own engaging feature in the conical connection.
Platform Diameter	Ø 4. 6 mm	Ø 3.5 and 4.6 mm	Ø 3.5 and 4.6 mm	Equivalent Into the range of the reference devices'.
Gingival Heights	1.5, 2.5, 3.5 and 4.5 mm	1.0, 2.5 and 4.0 mm	1.0, 2.5, 4.0 and 5.5 mm	Equivalent The gingival heights of the subject devices are into the range of the reference devices'.
Angulation	0, 17 and 30°	0, 17 and 30°	0, 17 and 30°	Identical
Sterilization Method	Sterile by gamma radiation	Non-sterile/ End user sterilized	Sterile by gamma radiation	Identical To one of the reference devices.
Prosthesis type	Screw-retained	Screw-retained	Screw-retained	Identical.

Table 2 – Comparison matrix: subject device versus reference device (SRAs)

FEATURE	PROPOSED DEVICE	REFERENCE PREDICATE DEVICE	EQUIVALENCE DISCUSSION
	Subject Device – BLX Anatomic Abutments	**K071357 (Straumann anatomic abutments)**	
Material	Ti-6Al-7Nb	Ti	Equivalent Both materials are titanium based. Differences in safety and performance are addressed via biocompatibility and fatigue assessment.
Implant to Abutment Connection	BLX (with conical fitting)	CrossFit® (NC) (with conical fitting)	Equivalent The subject devices have a conical implant-to-abutment fitting as well as the reference devices, nevertheless, each implant system has its own engaging feature in the conical connection.
Gingival Heights	2.5 and 3.5 mm	2 and 3.5 mm	Equivalent The gingival heights of the subject devices are into the range of the reference devices'.
Total abutment height	13.4 to 15.1 mm	10.4 to 12.3 mm	Equivalent All heights are compatible with anatomical conditions. Differences in the performance are addressed via fatigue performance assessment.
Angulation	0 and 17°	0 and 15°	Equivalent The difference in the angulation is addressed via performance assessment.
Sterilization Method	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized	Identical.
Prosthesis type	Cement-retained	Cement-retained	Identical.

Table 3 – Comparison matrix: subject device versus reference device (Anatomic Abutments)

Performance Testing

The following performance data support the substantial equivalence determination.

Sterilization Validation and Shelf Life

The BLX implants and SRAs are provided sterile via gamma irradiation at a dose of 25 kilogray (2.5 Mrad) minimum. A sterility assurance level (SAL) of 10^{-6} has been validated in accordance with ISO 11137-1:2006, *Sterilization of health care products –*

Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, 2006-04-05. The validation method used was the over kill bioburden method in accordance with ISO 11137-2:2013, *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*.

The packaging of the BLX sterile devices is equivalent to the packaging of the predicate and reference device and the shelf life is 5 years when considering that the materials are not adversely affected by time.

There are no changes to the sterilization method or processes when compared to the Straumann predicate devices.

The BLX Anatomic 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".

Pyrogenicity information provided is based on FDA Guidance on "*Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile*, issued on 21 January 2016." The method used to determine the device meets pyrogen limit specifications is LAL Endotoxin Analysis with testing limit of 20 EU/device, based on a blood contacting and implanted device.

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 and reference predicate devices and therefore no new testing has been performed.

Bench Testing

Dynamic fatigue, static strength, and insertion torque 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 BLX Implant System is equivalent to the predicate and reference devices.

Dynamic fatigue (and static strength) tests were performed to evaluate the fatigue load limits of the proposed Straumann BLX Implants. Based on worst-case considerations, both platforms RB and WB were tested and shown to be equivalent to the reference devices.

Insertion torque tests were conducted on the worst cases defined for BLX implants Ø3.75 mm. With this test, it was demonstrated that the BLX Implants and the related cutting instruments allow reaching suitable implant insertion torques.

Clinical data

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

Conclusion

The documentation submitted in this premarket notification demonstrates the Straumann® BLX implants, SRAs and Anatomic Abutments are substantially equivalent to the primary predicate and reference devices.