December 27, 2019

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

Re: K191256
Trade/Device Name: Straumann BLX Ø3.5 mm Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: November 22, 2019
Received: November 25, 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,

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)*

K191256

Device Name:

Straumann BLX Ø3.5 mm Implants

Indications for Use *(Describe)*

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 by the corresponding abutment components.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration

Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov*

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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
Prepared By & Alternate Contact:	Ana C. M. Vianna Regulatory Affairs and Compliance Manager Institut Straumann AG Phone number : +41 61 965 1259
Date of Submission:	December 26, 2019

5.2 Name of the Device

Trade Names:	Straumann BLX Ø3.5 mm Implants
Common Name:	Endosseous dental implant
Classification Name:	Endosseous dental implant
Regulation Number:	§872.3640
Device Classification:	II
Product Code(s):	DZE
Classification Panel:	Dental

5.3 Predicate Device(s)

Primary Predicate:

- *K181703 - Straumann BLX Line Extension - Implants, SRAs and Anatomic Abutments*

Reference Devices:

- *K130222 - Straumann Dental Implant System*

5.4 Device Description

The Straumann BLX Ø3.5 mm Implants are fully tapered implants manufactured utilizing the Roxolid material and are finished with SLActive® surface. The BLX connection is identified as conical fitting with Torx style engaging feature (TorcFit connection). There are two available prosthetic platforms identified for BLX Implants: RB (Regular Base) and WB (Wide Base). The subject devices have a RB platform with a TorcFit 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	Maximium outer Ø (mm)	Length (mm)
RB	3.5	8
		10
		12
		14
		16
		18

5.5 Intended Use

The Straumann dental implants are suitable for endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of patients with missing teeth.

5.6 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 by the corresponding abutment components.

5.7 Technological Characteristics

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	PRIMARY PREDICATE DEVICE
K Number	**Straumann BLX Ø3.5 mm Implants**	**K181703**	**K130222**
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 by the corresponding abutment components.	The 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 Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).
Material	Roxolid	Roxolid	Roxolid
Surface Treatment	SLActive®	SLActive®	SLActive®
Implant to Abutment Connection	BLX TorcFit connection	BLX TorcFit connection	RN, WN, NC, RC
Implant Diameter	3.5 mm	3.75 mm	3.3 to 4.8 mm
Implant Length	8 to 18 mm	8 to 18 mm	6 to 16 mm
Implant Design	BLX fully tapered body	BLX fully tapered body	Cylindrical and partially tapered
Sterilization Method	Irradiation	Irradiation	Irradiation

Table 1 – Comparison of subject device versus primary predicate device (Dental Implants)

5.8 Performance Testing

5.8.1 Sterilization Validation and Shelf Life

The BLX implants 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 subject devices will not be marketed as non-pyrogenic. The method used to make the determination that the device meets pyrogen limit specifications is LAL Endotoxin Analysis. The testing limit is 20 EU/device.

The packaging of the subject devices is equivalent to the packaging of the predicate devices 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.

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 equivalent nature of body contact, contact duration, material formulation and sterilization methods compared to the primary predicate devices and therefore no new testing has been performed.

5.8.3 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 devices.

Dynamic fatigue (and static strength) tests were performed to evaluate the fatigue load limits of the proposed Straumann BLX Implants. The test environment was 0.9% NaCl at 37°. The results show the subject devices are equivalent to the predicate devices.

Insertion torque tests were conducted on the worst cases defined for BLX Ø3.5 mm implants.

With this test, it was demonstrated that the BLX Implants and the related cutting instruments allow reaching suitable implant insertion torques.

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 Straumann BLX Ø3.5 mm implants are substantially equivalent to the primary predicate devices.