June 21, 2021

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

Re: K210855
Trade/Device Name: Straumann BLX Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: March 22, 2021
Received: March 23, 2021

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 I. Steen
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210855

Device Name

Straumann BLX Implant System

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 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 used are connected to the implants through 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.

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510(k) Summary

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 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:	Viviana Horhoiu Regulatory Affairs and Compliance Manager Institut Straumann AG Phone number: +41 61 965 1260
Date of Submission:	June 21, 2021

Name of the Device

Trade Names:	Straumann® BLX Implant System
Common Name:	Endosseous dental implant
Classification Name:	Endosseous dental implant
Regulation Number:	§872.3640
Device Classification:	II
Product Code(s):	DZE

Predicate Device(s)

Primary Predicate:

- *K181703 – Straumann BLX Line Extension – Implants, SRAs, and Anatomic Abutments (Institut Straumann AG)*

Reference Devices:

- *K200586 – Straumann TLX Implant System (Institut Straumann AG)*
- *K150938 – Straumann Dental Implant System – Roxolid SLA Implants (Institut Straumann AG)*

Device Description

The BLX Implants are fully tapered implants manufactured utilizing the Roxolid material and finished with the SLA or SLActive surface. The connection is identified as conical fitting with the Torx style engaging feature. The subject BLX implants have endosteal implant diameters of Ø3.75 and Ø4.0 mm with a length of 6 mm and are presented with one prosthetic platform:

- RB (Regular Base)

The internal connection and the prosthetic platform are identical for all subject devices.

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 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 used are connected to the implants through the corresponding abutment components.

Technological Characteristics

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

K210855 – Traditional 510(k)

Straumann® BLX Implant System

510(k) Summary

Feature	Proposed Device	Primary Predicate Device	Primary Predicate Device	Reference Device
	Subject Straumann BLX Implant System	**K181703 Straumann BLX Line Extension – Implants, SRAs, and Anatomic Abutments**	**K200586 Straumann TLX Implant System**	**K150938 Straumann Dental Implant System – Roxolid SLA**
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 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 used 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, 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 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.	Straumann® dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used 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 by the corresponding elements (abutments).
Material	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)
Surface Treatment	Hydrophilic SLActive® and SLA®	Hydrophilic SLActive®	Hydrophilic SLActive®	SLA®
Implant to Abutment Connection	TorcFit (with conical fitting)	TorcFit (with conical fitting)	TorcFit (with conical fitting)	CrossFit
Implant Diameter	Ø3.75 and 4.0 mm	Ø3.75 mm	Ø3.75, 4.0, 4.5, 5.0, 5.5, and 6.5 mm	Ø 3.3, 4.1, and 4.8 mm

Feature	Proposed Device	Primary Predicate Device	Primary Predicate Device	Reference Device
	Subject Straumann BLX Implant System	**K181703 Straumann BLX Line Extension – Implants, SRAs, and Anatomic Abutments**	**K200586 Straumann TLX Implant System**	**K150938 Straumann Dental Implant System – Roxolid SLA**
Implant Length	6 mm	8, 10, 12, 14, 16, and 18 mm	**Ø3.75, 4.0, 4.5, 5.0 mm:** 6, 8, 10, 12, 14, 16 and 18 mm **Ø5.5 and 6.5 mm:** 6, 8, 10, 12 mm	6, 8, 10, 12, 14 and 16 mm
Implant Design	Tapered body	Tapered body	Tapered body	Parallel and tapered body
Prosthetic platforms	RB	RB	NT, RT, and WT	N/A
Sterilization Method	Irradiation	Irradiation	Irradiation	Irradiation
MR Labeling	MR Conditional	N/A	MR Conditional	N/A

Table 1 – Comparison of subject device versus predicate devices – BLX Implant System

Performance Testing

Bench Testing

Dynamic fatigue testing 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"* and demonstrated the subject BLX Implants System is equivalent to the predicate and reference devices. The test was conducted in saline (2 Hz and 37°C) at 2 million cycles covering permanent restoration of the implant without failure.

Insertion tests were performed for the subject devices and it could be proven that there is an adequate insertion torque in different bone classes when the implant is inserted according to the surgical procedure.

Surface area comparison and pull-out testing were leveraged from K200586 as the endosseous surface area of the subject implants is identical to the referenced implants from K200586.

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 device materials are identical to the predicate and reference device materials, therefore, no new issues regarding biocompatibility were raised.

Sterilization Validation and Packaging

The sterilization process for the subject BLX Implant System as recommended in the labeling was validated to a sterility assurance level (SAL) of 10^{-6} 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 subject BLX Implant System is equivalent to the packaging of the predicate and reference device. The shelf life for devices provided sterile is 5 years. The devices will not be marketed as non-pyrogenic. 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.

Conclusion

The documentation submitted in this premarket notification demonstrates the subject Straumann BLX Implant System is substantially equivalent to the primary predicate and reference devices.