January 28, 2022

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

Re: K212533
Trade/Device Name: BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: December 23, 2021
Received: December 27, 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)*
K212533

Device Name:

BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants

Indications for Use *(Describe)*

Straumann® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.

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

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:	Corinne Arimatea Regulatory Affairs and Compliance Manager Institut Straumann AG Phone Number: +41 61 965 1217
Date of Submission:	January 28, 2022

Name of the Device

Trade Names:	BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) 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

K212533

BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants

510(k) Summary

Predicate Device(s)

Primary Predicate:

- *K130222 – Straumann Dental Implant Systems*

Reference Device:

- *K173961 - Straumann BLX Implant System*
- *K200586 – Straumann TLX Implant System*
- *K140091 - Xpeed Anyridge Internal Implant Systems*
- *K190662 - MRI Compatibility for Existing Straumann Dental Implant Systems*

Device Description

The subject devices are part of the BLX implant line, a fully tapered implant manufactured out of Roxolid and having the SLActive or SLA surface. The connection is identified as conical fitting with the Torx style engaging feature. The subject BLX implants have endosteal implant diameters of Ø5.0mm and lengths of 18 mm and diameters of Ø5.5mm and Ø6.5mm and lengths of 14 mm and 16 mm. The subject devices are presented with the WB (Wide Base) prosthetic platform. The internal connection and the prosthetic platform are identical for all subject devices.

Intended Use

The Straumann® dental implants and abutments are intended for oral implantation to provide a support structure for connected prosthetic devices.

Indications for Use

Straumann® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.

Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate devices in Table 1. The Ø6.5 x 16 mm subject implant is longer than the predicate and reference devices. As such, the surgical procedure has been updated to provide further guidance for protection of critical anatomical structures:

> "The vertical bone availability determines the maximum allowable length of the implant that can be placed. A minimum distance of 2 mm between the apex of the implant and the alveolar nerve should be kept. For easier determination of the vertical bone availability, we recommend the use of an x-ray reference foil with X-ray Reference Sphere (049.076V4)."

The Instructions for Use were also updated to include the following caution/precaution:

> "Larger size implants are recommended for the molar region only."

The Indications for Use Statement is similar between the subject and primary predicate devices. The subject submission does not include abutments; therefore, the last sentence of the primary predicate Indications for Use has been omitted from the subject device Indications for Use. The other differences are minor wording changes that do not change the intended meaning of the Indications for Use.

The reference device K190662 is included for reference to the MRI compatibility.

BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants

510(k) Summary

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE (BLX IMPLANTS)	REFERENCE DEVICE (TLX IMPLANTS)	REFERENCE DEVICE (XPEED ANYRIDGE IMPLANTS)
K Number	**K212533**	**K130222**	**K173961**	**K200586**	**K140091**
Indications for Use	Straumann® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.	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).	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.	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.	The Xpeed AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.

BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants

510(k) Summary

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE (BLX IMPLANTS)	REFERENCE DEVICE (TLX IMPLANTS)	REFERENCE DEVICE (XPEED ANYRIDGE IMPLANTS)
K Number	**K212533**	**K130222**	**K173961**	**K200586**	**K140091**
Material	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	CP Ti Grade 4
Surface Treatment	Hydrophilic SLActive® and SLA®	Hydrophilic SLActive®	Hydrophilic SLActive® and SLA® (SLA® introduce by Memo-to-File)	Hydrophilic SLActive®	SLA®
Implant to Abutment Connection	TorcFit (with conical fitting)	SynOcta and CrossFit	TorcFit (with conical fitting)	TorcFit (with conical fitting)	n/a
Implant Diameter	Ø5.0, 5.5 and 6.5 mm	Ø3.3, Ø4.1, Ø4.8, and Ø4.8 for TL (S, SP, TE) Ø3.3, Ø4.1 and Ø4.8, BL	Ø 4.5, 5.5, 6.5 mm	Ø3.75, 4.0, 4.5, 5.0, 5.5, and 6.5 mm	For normal ridge: 4.0, 4.4, 4.9, 5.4 & 5.9 mm For low ridge: 6.4, 6.9, 7.4, 7.9 & 8.4 mm
Implant Length	Ø5.0 mm: 18 mm Ø5.5 and 6.5 mm: 14 and 16mm	6.0, 8.0, 10.0, 12.0, 14.0 & 16.0 mm	Ø4.5 mm: 6, 8, 10, 12, 14, 16 and 18 mm Ø5.5 and 6.5 mm: 6, 8, 10, 12 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	For normal ridge: 7.7, 9.2, 10.7, 12.2, 14.20 & 17.2 mm For low ridge: 7.9, 9.4, 10.9, 12.4 & 14.4 mm
Implant Design	Tapered body	Cylindrical	Tapered body	Tapered body	n/a
Sterilization Method	Irradiation	Irradiation	Irradiation	Irradiation	Irradiation

Table 1 – Comparison of subject device versus primary predicate device

Performance Testing

Bench Testing

An assessment regarding dynamic fatigue testing was conducted according to the FDA guidance document G*uidance 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 do not introduce a new worst case compared to the reference device device. Therefore, dynamic fatigue testing was leveraged from the reference device K173961.

Insertion tests were performed for the subject implants and proved that there is an adequate insertion torque in different bone classes when the implant is inserted according to the surgical procedure. Insertion torque results are equivalent to the primary predicate device.

Biocompatibility Testing

A biological assessment was 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. No new issues of biocompatibility are raised for the subject devices. Therefore, no additional biocompatibility testing was required.

Sterilization Validation and Packaging

The sterilization process for the subject implants 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*. 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 identical to the packaging of the primary predicate devices. 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 BLX WB implants are substantially equivalent to the primary and reference devices.