March 20, 2024

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

Re: K234049
Trade/Device Name: Straumann® BLC and TLC Implants - Line extension
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: December 21, 2023
Received: December 21, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234049

Device Name

Straumann® BLC and TLC Implants - Line extension

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510(k) Submission - K234049

Straumann® BLC and TLC Implants - Line extension

510(k) Summary

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 On the behalf of: Institut Straumann AG Peter Merian Weg 12 4052 Basel, Switzerland
Contact Person:	Jennifer M. Jackson, MS, RAC Sr. Director, Regulatory Affairs and Quality Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023
Prepared By & Alternate Contact:	Laure Kuhner Borsenberger Regulatory Affairs and Compliance Manager Institut Straumann AG Phone number: +41 79 828 9414
Date of Submission:	March 19, 2024

2 Name of the Device

Trade Names:	Straumann® BLC and TLC Implants - Line extension
Common Name:	Endosseous Dental Implant
Classification Name:	Endosseous Dental Implant
Regulation Number:	§872.3640
Device Classification:	II
Product Code(s):	DZE
Classification Panel:	Dental

3 Predicate Device(s)

Primary Predicate:

- *K230108 - Straumann® BLC and TLC Implants*

Reference Devices:

- *K212533 - BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants*

4 Device Description

The subject devices are part of the Straumann® Dental Implant System, which is an integrated system of endosseous dental implants with corresponding abutments and healing components as well as instruments and prosthetic parts. Straumann® dental implants are solid screw implants with a bone anchorage surface that is large-grit sandblasted and acid-etched. In addition, SLActive® is in a chemically activated state, which is preserved by storage in a saline solution (NaCl). Straumann® dental implants can be used following the extraction or loss of natural teeth to restore chewing function. The prosthetic restorations supported are single crowns, bridges and partial or full dentures, which are connected to the implants using the corresponding abutments.

The purpose of this premarket notification is to extend the BLC and TLC Implants portfolio by including new sizes of implants, more specifically:

BLC implants:

- L 16 mm for diameter ø 6.5 mm, presented with WB (Wide Base) prosthetic platform.

TLC implants:

- L 14 mm and L 16 mm for diameter ø 5.5 mm, with both implant neck options - Standard (2.8 mm height) and Standard Plus (1.8 mm height)
- L 8 mm and L 10 mm for diameter ø 6.5 mm and implant neck Standard (2.8 mm height)
- L 12 mm to L 16 mm for diameter ø 6.5 mm, with both implant neck options - Standard (2.8 mm height) and Standard Plus (1.8 mm height)

and presented with WT (Wide TorcFit) prosthetic platform.

The submission also introduces a new sterilization method using X-ray irradiation which was validated on worst-case test articles representative of the BLC and TLC implant systems.

A summary of the diameter/length implant body combinations is given in Table 1.

	BLC implant	TLC implant	
Implant Diameter	ø 6.5mm	ø 5.5mm	ø 6.5mm
Implant Length	-	-	8 mm - S
	-	-	10 mm - S
	-	-	12 mm - S & SP
	-	14 mm - S & SP	14 mm - S & SP
	16 mm	16 mm - S & SP	16 mm - S & SP
Prosthetic platforms	WB	WT	WT

Table 1 – Overview of diameter/length implant body combinations

5 Intended Use

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

6 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.

7 Technological Characteristics

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

Traditional 510(k) Submission - K234049

Straumann® BLC and TLC Implants - Line extension

510(k) Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number/ name	**K234049** **BLC & TLC Implant Line extension**	**K230108** **Straumann® BLC and TLC Implants**	**K212533** **BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants**	
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 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 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.	Identical to primary predicate and reference device
Material	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	Identical to primary predicate and reference device
Surface Treatment	Hydrophilic SLActive®	Hydrophilic SLActive® and SLA®	Hydrophilic SLActive® and SLA®	Identical to primary predicate and reference device
Implant to Abutment Connection	TorcFit (with conical fitting)	TorcFit (with conical fitting)	TorcFit (with conical fitting)	Identical to primary predicate and reference device
Implant Diameter and Length	BLC implants: Ø 6.5: 16 mm TLC implants: Ø 5.5: 14 and 16 mm (S and SP) Ø 6.5: 8 and 10 mm (S only) Ø 6.5: 12, 14, 16 mm (S and SP)	BLC implants: Ø 3.3: 8, 10, 12, 14, 16, 18 mm Ø 3.75 and 4.5: 6, 8, 10, 12, 14, 16, 18 mm Ø 5.5: 6, 8, 10, 12, 14, 16 mm Ø 6.5: 6, 8, 10, 12, 14 mm TLC implants: Ø 3.3: 8, 10, 12, 14, 16, 18 mm (S and SP) Ø3.75 and 4.5: 6, 8, 10, 12, 14, 16, 18 mm (S and SP) Ø 5.5: 6, 8, 10, 12 mm (S and SP) Ø 6.5: 6 mm (S and SP) Ø 6.5: 8 and 10 mm (SP only)	Ø 5.0: 18 mm Ø 5.5 and 6.5: 14 and 16 mm	Extension of primary predicate, implantable dimensions identical to reference device

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number/ name	**K234049 BLC & TLC Implant Line extension**	**K230108 Straumann® BLC and TLC Implants**	**K212533 BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants**	
Implant Design	Apically tapered Bone Level implant and Apically tapered Tissue Level implant	Apically tapered Bone Level implant and Apically tapered Tissue Level implant	Fully tapered Bone Level implant	Identical to primary predicate
Thread Pitch	1.15 mm	0.8, 0.9, 1 and 1.15 mm	2.5 to 3.1 mm	Identical to primary predicate
Sterilization Method	Irradiation (gamma and x-ray)	Irradiation (gamma)	Irradiation (gamma)	Equivalent to primary predicate and reference device. The two sterilization methods are comparable in terms of their sterilization principle (photons), with some technical advantages for X-ray such better dose uniformity, less oxidative stress for certain materials and processing time. Both methods are validated by Straumann.

Table 2 – Comparison matrix: subject device versus primary predicate and reference device

8 Performance Testing

Sterilization Validation and Shelf-life

The subject devices are provided sterile via gamma irradiation at a dose of 25 kGy and will be sterilized after final packaging. The sterilization process for the subject devices 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 (or $VD_{max}25$) method in accordance with ISO 11137- 2:2013, "Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose". There are no changes to the gamma irradiation sterilization procedures or processes from those of the Straumann primary predicate devices (K230108), the subject devices do not represent a higher challenge to the sterilization process in comparison to the validated worst-case product and validated gamma irradiation sterilization process.

In addition, a validation of the X-ray irradiation as a new sterilization method was conducted. The validation method used was the $VD_{max}25$. A sterility assurance level (SAL) of 10^{-6} was validated in compliance 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* and ISO 11137-2:2013, *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*.

The packaging of the subject device is equivalent to the packaging of the primary 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.

Biocompatibility Testing

Biological assessment has been performed according to ISO 10993-1 “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 are equivalent in material, surface, manufacturing process, packaging materials, sterilization by gamma irradiation, body contact and contact duration compared to the reference device K230108. Sterilization by X-ray irradiation was validated and may be used as an alternative sterilization method instead of gamma irradiation. The impact on the biological safety was evaluated and the needed biocompatibility testing was determined according to the ISO 10993-1:2018 standard. The results of the conducted tests have demonstrated that the assessed devices do not show any reactions with X-ray sterilization that could have a biological effect on the patient at T0 (no aging), T3 (3 years accelerated aging) and T5 (5 years accelerated aging for long-term effect). Thus, the subject devices are considered biologically safe for their intended use according to ISO 10993-1 and FDA's guidance document of ISO 10993-1.

Electromagnetic Compatibility

There are no significant changes to the materials and dimensions from the currently marketed predicate devices. Therefore, no new issues of electromagnetic compatibility are raised for the subject devices and they can be considered MR Conditional.

The subject implants have obtained the status of MR Conditional per K180540. The MR Conditional tests were conducted according to FDA’s Guidance “Testing and Labeling Medical Devices for Safety in Magnetic Resonance (MR) Environment”.

Performance Testing – Bench

Insertion tests were performed for the subject implants 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.

The subject device surface treatments are identical to the surface treatments of the primary predicate and reference devices. The SLActive® surface treatment is a sand-blasted, large grit, acid etched, chemically active and hydrophilic surface. The surface is routinely tested by roughness measurement or scanning electron microscopy.

Conclusion

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