4/8/2022

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

Re: K213063
Trade/Device Name: TLX SRAs and TLX Gold Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 9, 2022
Received: March 11, 2022

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,

for Andrew 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)*
K213063

Device Name
TLX SRAs and TLX Gold Abutments

Indications for Use *(Describe)*

TLX SRAs

Straumann® abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of edentulous or partially edentulous patients with crowns, bridges or full-arch prostheses.

TLX Gold Abutments

Straumann® abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of edentulous or partially edentulous patients with crowns, bridges or full-arch prostheses.

Copings are indirectly connected to the endosseous dental implant and are indicated for use as an aid in prosthetic rehabilitations.

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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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 & Alternate Contact:	Yu-Ting Chang International Regulatory Affairs Manager Institut Straumann AG Phone number: +41 61 965 1318
Date of Submission:	April 8, 2022

Name of the Device

Trade Names:	TLX SRAs and TLX Gold Abutments
Common Name:	Endosseous Dental Implant Abutments
Classification Name:	Endosseous Dental Implant Abutments
Regulation Number:	§872.3630
Device Classification:	II
Product Code(s):	NHA
Classification Panel:	Dental
Proprietary Name:	TLX SRAs and TLX Gold Abutments

K213063 – Traditional 510(k)

TLX SRAs and TLX Gold Abutments

510(k) Summary

Predicate Device(s)

Primary Predicate:

- *K203355 - Straumann TLX Novaloc and Cementable Abutments - Cementable Abutments*

Reference Devices:

- *K181703 - Straumann® BLX Line Extension – Implants, SRAs, and Anatomic Abutments - SRAs*
- *K200597 - BLX Gold Abutments*

Device Description

TLX SRAs

Straumann® TLX SRAs are intended to be placed on TLX Straumann dental implants to provide support for screw-retained single or multi-unit restorations. They are identical in design to the reference devices BLX SRAs cleared as per K181703, except for the laser marking and the anodization. The TLX SRAs have no anodization, but additional laser marking at the connection. The TLX SRAs are provided sterile by gamma radiation. The TLX SRAs are made of TAN (Ti-6Al-7Nb) and are available in angulations of 17° and 30°. The TLX SRAs are secured in the implant through a basal screw made of TAN. The SRAs are provided with a transfer piece (Pin).

TLX Gold Abutments

Straumann TLX Gold Abutments consist of a Ceramicor® alloy base, which is fixed to the implant by means of a basal screw made of Ti-6Al-7Nb, Titanium Aluminum Niobium (TAN). A modelling aid made of POM-C is attached onto the abutment by friction fit when delivered in the package. There are two versions of TLX Gold Abutments: one is for single crown restoration, and the other is for multiunit restoration such as bar or bridge. The TLX Gold Abutments for crown contain the TorcFit connection which provides the rotational indexation. On the other hand, the TLX Gold Abutments for bar/bridge do not have the TorcFit indexation feature since it is used in multiunit restorations. Both versions are available in three different platform diameters, NT (Narrow, TorcFit™), RT (Regular, TorcFit™) and WT (Wide, TorcFit™), allowing the abutments to sit on the shoulders of the corresponding TLX implants. The TLX Gold

Abutments have a maximum angulation of 30°, a minimum post height of 4 mm, and a minimum wall thickness of 0.7 mm.

Intended Use

TLX SRAs

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

TLX Gold Abutments

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

Copings are indirectly connected to the endosseous dental implant and are indicated for use as an aid in prosthetic rehabilitations.

Indications for Use

TLX SRAs

Straumann® abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of edentulous or partially edentulous patients with crowns, bridges, or full-arch prostheses.

TLX Gold Abutments

Straumann® abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of edentulous or partially edentulous patients with crowns, bridges, or full-arch prostheses.

Copings are indirectly connected to the endosseous dental implant and are indicated for use as an aid in prosthetic rehabilitations.

Technological Characteristics

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

K213063 – Traditional 510(k)

TLX SRAs and TLX Gold Abutments

510(k) Summary

TLX SRAs

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number	**K213063** **Straumann TLX SRAs**	**K203355** **Straumann TLX Cementable Abutments**	**K181703** **Straumann BLX SRAs**	
Indications for Use	Straumann® abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of edentulous or partially edentulous patients with crowns, bridges, or full-arch prostheses.	Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Final abutments may be placed into occlusion for implants with sufficient primary stability and with appropriate occlusal loading to restore chewing function or for implants that are fully osseointegrated	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.	**Equivalent.** All allow the abutment to be place/connected to dental implants and the purpose is to aid/support the prosthetic rehabilitation. The subject device provides more detail regarding the type of rehabilitation These are also implicitly covered under primary predicate and reference device. The final abutment placement recommendation of the subject device was moved from the Indications for Use Statement to the Caution/Precautions section of the Instructions for Use since the loading of the implant body is inherent to the Indications for Use of the overarching implant body clearance. Therefore, the scope is the same among subject, primary predicate, and reference devices.
Material	Ti-6Al-7Nb (TAN)	Ti-6Al-7Nb (TAN)	Ti-6Al-7Nb (TAN)	**Identical**
Implant to Abutment Connection	TLX TorcFit	TLX TorcFit	BLX TorcFit	**Identical** Identical to the primary predicate device.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number	**K213063 Straumann TLX SRAs**	**K203355 Straumann TLX Cementable Abutments**	**K181703 Straumann BLX SRAs**	
Platform Diameter	Ø4.6 mm	4.0 (NT), 5.0 (RT) and 7.0 (WT)	Ø4.6 mm	**Identical** Identical to the reference device
Platform	NT	NT, RT, and WT	RB/WB	**Identical** Identical to the primary predicate device.
Heights	3.5 mm	Straight: 5,7 and 6 mm Angled: 6 mm	1.5, 2.5, 3.5 and 4.5 mm	**Identical** Identical to the reference device
Angulation	17° and 30°	0° and 15	0°, 17° and 30°	**Identical** Identical to the reference device
Sterilization Method	Sterile by gamma radiation	Non-sterile	Sterile by gamma radiation	**Identical** Identical to the reference device
Prosthesis type	Screw-retained	Cemented-retained	Screw-retained	**Identical** Identical to the reference device
Surface	Not anodized	Not anodized	Anodized	**Identical** Identical to the primary predicate device.
Shelf life	5 years	Without defined shelf life	5 years	**Identical** Identical to the reference device
Packaging	Sterile barrier system (blister) protected by folding box	Non-sterile blister	Sterile barrier system (blister) protected by folding box	**Identical** Identical to the reference device

Table 1 – Comparison of subject device versus primary predicate and reference device (SRAs)

TLX Gold Abutments

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number	**K213063** **Straumann TLX Gold Abutments**	**K203355** **Straumann TLX Cementable Abutments**	**K200597** **BLX Gold Abutments**	
Indications for Use	Straumann® abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of edentulous or partially edentulous patients with crowns, bridges or full-arch prostheses. Copings are indirectly connected to the endosseous dental implant and are indicated for use as an aid in prosthetic rehabilitations.	Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Final abutments may be placed into occlusion for implants with sufficient primary stability and with appropriate occlusal loading to restore chewing function or for implants that are fully osseointegrated	Straumann abutments are intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns, bridges, and overdentures.	**Equivalent.** All allow the abutment to be placed/connected to dental implants for the purpose of aiding/supporting the prosthetic rehabilitation. The subject device Indications for Use provides more detail concerning the rehabilitation. The indications are also covered under the primary predicate and reference devices Indications for Use. The final abutment placement recommendation for the subject devices was moved from the Indications for Use Statement to the Caution/Precautions section of the Instructions for Use since the loading of the implant body is inherent to the Indications for Use of the overarching implant body clearance. The scope of the Indications for Use is the same among subject, primary predicate, and reference devices.
Material	Ceramicor® (base) TAN (screw) POM (modeling aid)	Ti-6Al-7Nb (TAN)	Ceramicor® (base) TAN (screw) POM (modeling aid)	**Identical** Identical to the reference device.

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TLX SRAs and TLX Gold Abutments

510(k) Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number	**K213063 Straumann TLX Gold Abutments**	**K203355 Straumann TLX Cementable Abutments**	**K200597 BLX Gold Abutments**	
Abutment Shape in Coronal Portion	Axial screw access hole for placement of abutment into implant	Axial screw access hole for placement of abutment into implant	Axial screw access hole for placement of abutment into implant	**Identical** Identical to the primary predicate and reference device.
Abutment to Implant Connection	TLX TorcFit	TLX TorcFit	BLX TorcFit	**Identical** Identical to the primary predicate device.
Platform Diameter (mm)	4.0 (NT), 5.0 (RT) and 7.0 (WT)	4.0 (NT), 5.0 (RT) and 7.0 (WT)	RB/WB: 3.8 and 4.5 WB: 4.5 and 5.5	**Identical** Identical to the primary predicate device.
Post Height of Stock Component	NT (3 mm), RT (3.6 mm) and WT (4 mm)	Straight: 5.7 and 6 mm Angled: 6 mm	RW/WB and WB: 2.6 mm	**Equivalent** The post heights are equivalent to the reference device. In both cases, the post provides the initial support for casting.
Wall thickness	0.7*	n/a	0.7*	**Identical** Subject device and reference device have a minimum recommended wall thickness of 0.7mm, as described in the IFU
Angulation	0° and up to 30°** after customization	0° and 15°	0° and up to 30°** after customization	**Identical** Identical to the reference device.
Restoration Type	Crown, Bridge and Full Arch	Crown, Bridge and Full Arch	Crown, Bridge and Full Arch	**Identical** Identical to the primary predicate device.
Sterilization Method	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized	**Identical** Identical to the primary predicate device.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number	**K213063** **Straumann TLX Gold Abutments**	**K203355** **Straumann TLX Cementable Abutments**	**K200597** **BLX Gold Abutments**	
Surface	Not anodized	Not anodized	Not anodized	**Identical** Identical to the primary predicate device.
Restoration Type	Cemented or screw-retained	Cemented-retained	Cemented or screw-retained	**Identical** Identical to the reference device.

*Given by the wall thickness upon casting

**Abutments are provided straight (i.e., 0°) but may have an angulation of up to 30° upon casting

Table 2 – Comparison of subject device versus primary predicate and reference device (Gold Abutments)

Performance Testing

Bench Testing

An assessment regarding dynamic fatigue testing was conducted according to ISO 14801, *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants* and 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 TLX SRAs and Gold Abutments are equivalent to the primary predicate and reference devices.*

The test for the Gold Abutments was conducted in saline (2 Hz and 37°C) at 2 million cycles covering permanent restoration of the implant without failure. The test for the SRA Abutments was a pre-test conducted in ambient air (15 Hz and room temperature) at 5 million cycles covering permanent restoration of the implant without failure.

Biocompatibility Testing

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

Magnetic Resonance Compatibility

The reference devices K181703 and compatible prosthetics have obtained the status of MR Conditional. No new materials or worst-case constructs are introduced with the subject devices; thus, the previous MRI conditional wording is applicable.

Sterilization, Shelf-life, and Package

SRAs

The subject TLX SRAs are single patient devices and are provided sterile. The sterilization process for the subject TLX SRAs was validated to a sterility assurance level (SAL) of ≤ 10^{-6} in accordance with ISO 11137-1, *Sterilization of health care products – Radiation – Part 1:*

Requirements for development, validation, and routine control of a sterilization process for medical devices.

The shelf life for devices provided sterile is 5 years. The sterilization method and packaging of the subject TLX SRAs is identical to the reference devices K181703.

The subject 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.

Gold Abutments

The TLX Gold Abutments are single patient devices and are provided non-sterile. The sterilization procedures reflect the FDA guidance document, "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff, Document issued on: March 17, 2015*".

These sterilization parameters have been validated to a sterility assurance level (SAL) of $\leq 10^{-6}$ using the biological indicator (BI) overkill method for the product group, Implant Borne Prosthetics. The subject TLX Gold Abutments do not introduce a new worst case compared to the reference devices K200597.

Conclusion

The documentation submitted in this premarket notification demonstrates the subject TLX SRAs and Gold Abutments are substantially equivalent to the primary predicate devices.