June 16, 2022

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

Re: K220878
Trade/Device Name: Straumann® TLX Variobase® C
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: March 24, 2022
Received: March 25, 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,

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)*
K220878

Device Name

Straumann® TLX Variobase® C

Indications for Use *(Describe)*

The Straumann® TLX Variobase® C are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® TLX Variobase® C abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

All digitally designed copings and/or crowns for use with the Straumann® TLX Variobase® C abutments are to be designed using Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.

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 MerianWeg 12 CH-4002 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:	Gordon Dodds Manager Design Control QM Institut Straumann AG Phone number: +49 89 30 90 75 291
Date of Submission:	June 16, 2022

Name of the Device

Trade Names:	Straumann® TLX Variobase® C
Common Name:	Endosseous dental implant abutment (21 CFR 872.3630)
Classification Name:	Endosseous dental implant abutment (21 CFR 872.3630)
Regulation Number:	§872.3630
Device Classification:	II
Primary Product Code:	NHA
Secondary Product Code:	PNP
Classification Panel:	Dental

Predicate Device(s)

Primary Predicate:

- K192742 – Straumann Variobase C

Reference Devices:

- K181520 - Sirona Dental CAD/CAM System (Sirona Dental)
- K151324 - Variobase for CEREC (Institut Straumann AG)
- K200586 - Straumann TLX Implant System (Institut Straumann AG)
- K142890- Straumann Variobase (Institut Straumann AG)
- K190662 – MRI Compatibility for Existing Straumann Dental Implant Systems (Institut Straumann AG)

Device Description

The Straumann® TLX Variobase® C abutments are two-piece abutments composed of the following components:

- Straumann® TLX Variobase® C (Ti-base)
- Prosthetic Restoration (patient specific coping or crown)
- Basal Screw

The Straumann® TLX Variobase® C abutments provide the interface for copings or crowns designed and milled using a Sirona Dental CAD/CAM System with the Straumann dental implant platform: NT (Narrow TorcFit), RT (Regular TorcFit), and WT (Wide TorcFit). The Straumann® TLX Variobase® C abutments are pre-manufactured (stock) abutments, sometimes referred to as “Ti-bases,” made from a titanium-aluminum-niobium (TAN) alloy. The coronal portion is designed to interface with the pre-machined mounting hole in the milling blanks compatible with the Sirona MC XL prosthetic milling systems, and the base portion is available to fit the Straumann® dental implant platforms listed above. The top half material that is compatible with the Straumann® TLX Variobase® C abutments is IPS e.max CAD. The design parameters are provided in Table 1.

Abutment	Ivoclar IPS e.max CAD
Material minimum wall-thickness	0.8 mm
Maximum angle of restoration	20°
Minimum post height of crown	5.2 mm
Material duration of use	Permanent

Table 1 – Design parameters

PANAVIA F2.0 dental cement (K032455) is to be used for cementing the prosthetic restoration to the Straumann® TLX Variobase® C to complete the finished, two-piece CAD/CAM dental abutment.

Intended Use

Straumann® TLX Variobase® C abutments are intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns.

Indications for Use

The Straumann® TLX Variobase® C are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® TLX Variobase® C abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

All digitally designed copings and/or crowns for use with the Straumann® TLX Variobase® C abutments are to be designed using Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.

Technological Characteristics

As outlined in Table 1, the subject system includes a combination of previously cleared technologies that are now being implemented into one system. The Variobase C technology has received prior clearance for each Straumann implant body compatibility. The IPS e.max CAD material has received prior clearance for use as the second piece of a two-piece abutment under product code NHA and for use with the Sirona CAD/CAM digital workflow. Performance testing has addressed any differences resultant from new combinations of technologies.

The technological characteristics of the subject devices are compared to the primary predicate device in Table 2. The reference device K190662 is included for reference to MRI compatibility.

K220858

Straumann® TLX Variobase® C

510(k) Summary

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number		**K192742**	**K151324**	**K181520**	**K142890**	**K200586**
Indications for Use	The Straumann® TLX Variobase® C are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® TLX Variobase® C abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® TLX Variobase® C abutments are to be designed using Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit	The Straumann® Variobase® C are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® C abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase® C abutments are to be designed using Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.	The Straumann® Variobase® for CEREC® are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for CEREC® abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase® for CEREC® abutments are to be designed using Sirona inLab software (Version 3.65 or higher) or Sirona CEREC Software (Version 4.2 or higher) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. For the BH 3.0 S, SSO 3.5 L and SBL 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructure, and CAD/CAM software. Specifically, the inCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.XXXX) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the inCoris mesostructured. The inCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems:	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase™ Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.	TLX Dental Implant: 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. TLX Closure Caps and Healing Caps: Straumann Closure Caps and Healing Caps are indicated to be placed in the patient's mouth at the end of the implant placement to protect the inner configuration of the implant and to form, maintain and stabilize the soft tissue during the healing process. Closure caps and healing caps should be used only with suitable implant connections. They have a maximum duration of usage of 6 months. TLX Temporary Abutment: TLX Temporary Abutments 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. TLX Temporary Abutments have a maximum duration of usage of 180 days. TLX Variobase for Crown: Straumann Variobase prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. The prosthetic restoration (crowns) can be cemented onto the Straumann Variobase prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they must be placed out of occlusion. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated. All digitally designed copings and/or crowns for use with the Straumann Variobase Abutment system are intended to be sent to Straumann for manufacture at a validated milling center. TLX CARES Abutment TAN: The Straumann CARES Abutments TAN are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented. TLX Screw-retained Bridges and Bars: CARES Screw-retained Bridges and Bars (SRBB) are indicated for use as bars and bridges that attach to

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K Number		**K192742**	**K151324**	**K181520**	**K142890**	**K200586**
						implants to provide support for prosthetic reconstructions such as bridges and overdentures. The final processed products have the purpose of restoring chewing function. Straumann CARES Screw-retained Bridges and Bars are indicated for Screw-retained restorations. Straumann CARES Screw-retained Bridges and Bars are designed to interface with the Bone Level (BL), Tissue Level (TL), BLX implants and TLX implants of the Straumann Dental Implant System (SDIS).
Compatible Implants	Straumann TLX implants having the NT, RT and WT implant-to-abutment interface geometries.	Straumann Bone Level implants having the NC and RC implant-to-abutment interface geometries. Straumann Tissue Level implants having the NNC implant-to-abutment interface geometries. Straumann BLX implants having the RB/WB and WB implant-to-abutment interface geometries.	Straumann Bone Level implants having the NC and RC implant-to-abutment interface geometries. Straumann Tissue Level implants having the RN and WN implant-to-abutment interface geometries.	Nobel Biocare – Replace, Active, and Branemark Straumann – Synocta and Bone Level Dentsply Sirona Implants – Osseospeed, Xive, Osseospeed EV, and Ankylos Biomet 3i – Osseotite and Certain Zimmer – Tapered Screw-Vent Thommen Medical – SPI Element, SPI Element Inicell, SPI Contact Inicell Osstem/Hiossen – Osstem TS Implant System and Hiossen Implant System Biohorizons (Internal Connection	Straumann Bone Level implants having the NC and RC implant-to-abutment interface geometries. Straumann Tissue Level implants having the NNC, RN, and WN implant-to-abutment interface geometries.	Straumann TLX implants having the NT, RT and WT implant-to-abutment interface geometries.

Straumann® TLX Variobase® C

510(k) Summary

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number		**K192742**	**K151324**	**K181520**	**K142890**	**K200586**
Compatible Restoration Materials	Ivoclar IPS e.max CAD (S and L) – K132209	Sirona inCoris Zi meso (S and L) – K181520 Ivoclar IPS e.max CAD (S and L) – K132209 Straumann n!ce Glass Ceramic A14 Blocks (L) – K171773	Sirona inCoris Zi (L) – K062509 and K123664 Ivoclar IPS e.max CAD (S and L) – K132209 Ivoclar TelioCAD (S and L) – K093708	Sirona inCoris Zi (S and L)	Traditional Workflow: Type 4 Metals (ISO 22674) IPS e.max® Press Ceramic Digital Workflow: polycon® ae (temporary) zerion® (permanent) IPS e.max® CAD Ceramic (permanent) coron® (permanent)	Digital Workflow: polycon® ae (temporary) zerion LT (permanent)
Coronal Diameters	NT 2.98 mm (Size S) RT: 3.38 mm (Size L) WT 3.38 mm (Size L)	NC: 2.98 mm (Size S or L) RC: 3.38 mm (Size L) NNC: 2.98 mm (Size S) RB/WB: 2.98 mm (Size S) and 3.38 mm (Size L) WB: 3.38 mm (Size L)	NC: 3.38 mm (Size L) RC: 3.38 mm (Size L) RN: 3.38 mm (Size L) WN: 3.38 mm (Size L)	NC: 3.38 mm (Size L) RC: 3.38 mm (Size L)	NC: 2.80 mm RC: 2.90 mm NNC: 2.80 mm	NT 2.80 mm (3.9 mm diameter platform) RT 3.30 mm (5.05 mm diameter platform) WT 3.30 mm (7.00 mm diameter platform)
Abutment Platform Diameters	NT 4.0 mm RT 5.0 mm WT 7.0 mm	NC: 3.8 mm RC: 4.6 mm NNC: 3.9 mm RB/WB: 3.8 mm & 4.5mm WB: 5.5 mm	NC: 4.5 mm RC: 4.6 mm RN: 5.0 mm WN: 7.0 mm	3.0 – 7.0 mm	3.8 mm – 7.0 mm	NT 3.9 mm RT 5.05 mm WT 7.0 mm

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number		**K192742**	**K151324**	**K181520**	**K142890**	**K200586**
Stock Titanium Base Material	Titanium alloy (Ti-6Al-7Nb or TAN)	Titanium alloy (Ti-6Al-7Nb or TAN)	Titanium alloy (Ti-6Al-7Nb or TAN)	Titanium alloy	Titanium alloy (Ti-6Al-7Nb or TAN)	Titanium alloy (Ti-6Al-7Nb or TAN)
Construction	Two-piece abutment base with bonded prosthesis produced via the Sirona Dental CAD/CAM System digital workflow.	Two-piece abutment base with bonded prosthesis produced via the Sirona Dental CAD/CAM System digital workflow.	Two-piece abutment base with bonded prosthesis produced via the Sirona Dental CAD/CAM System digital workflow.	Two-piece abutment base with bonded prosthesis produced via the Sirona Dental CAD/CAM System digital workflow.	Two-piece abutment base with bonded prosthesis produced via traditional or CARES CAD/CAM digital workflow.	Two-piece abutment base with bonded prosthesis produced via traditional or CARES CAD/CAM digital workflow.
Maximum Angulation	20° controlled in design software	20° controlled in design software	20° controlled in design software	20° controlled in design software	30°	30°
Software	Sirona CEREC Software Version 5.2.4	Sirona CEREC Software Version 4.6.1	Sirona inLab software Version 3.65 or higher Sirona CEREC Software Version 4.2 or higher	CEREC SW version 4.6.1	N/A	N/A
Sterility	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.

Table 2 – Comparison of subject device versus primary predicate device –

Performance Testing

Dynamic fatigue and static strength 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 that the Straumann® TLX Variobase® C abutments are equivalent to the predicate and reference devices.

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

The sterilization process for the Straumann® TLX Variobase® C as recommended in the labeling was validated according to applicable recommendations in the FDA guidance document "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015"*.

Software verification and validation testing was provided for the subject abutment design library to demonstrate use with the Sirona Dental CAD/CAM System. Software verification and validation testing was conducted to demonstrate that the restrictions prevent design of the top half component of the two-piece abutment outside of the allowable design limitations, including screenshots under user verification testing. In addition, the encrypted abutment design library was validated to demonstrate that the established design limitations and specifications are locked and cannot be modified within the abutment design library.

Conclusion

The documentation submitted in this premarket notification demonstrates the Straumann® TLX Variobase® C abutments are substantially equivalent to the primary predicate and reference devices.