August 20, 2020

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

Re: K200586
Trade/Device Name: Straumann TLX Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 21, 2020
Received: July 22, 2020

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 Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K200586

Device Name
Straumann TLX Implant System

Indications for Use *(Describe)*

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 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).

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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# 5 510(k) Summary

## 5.1 Submitter's Contact Information

| | |
|---|---|
| Submitter: | Straumann USA, LLC (on behalf of Institut Straumann AG)<br>60 Minuteman Road<br>Andover, MA 01810<br>Registration No.: 1222315 Owner/Operator No.: 9005052<br><br>On the behalf of:<br>Institut Straumann AG<br>Peter Merian weg 12<br>4052 Basel, Switzerland |
| Contact Person: | Jennifer M. Jackson, MS<br>Director of Regulatory Affairs<br>Phone Number: +1-978-747-2509<br>Fax Number: +1-978-747-0023 |
| Prepared By: | Renate Reiss<br>Regulatory Affairs and Compliance Manager<br>Institut Straumann AG<br>Phone number: +41 61 965 1260 |
| Date Prepared: | August 19, 2020 |

## 5.2 Name of the Device

| | |
|---|---|
| Trade Names: | Straumann TLX Implant System |
| Common Name: | Endosseous dental implant |
| Classification Name: | Endosseous dental implant |
| Regulation Number: | §872.3640 |
| Device Classification: | II |
| Product Code(s): | Primary product code – DZE<br>Secondary product code – NHA |

## 5.3 Predicate Device(s)

Primary Predicate:

- K173961 – Straumann BLX Implant System

Reference Devices:

- K181703 – Straumann® BLX Line Extension
- K171784 – Straumann Dental implant system
- K190082 – Straumann BLX Variobase Abutment
- K190040 – BLX Line Extension – New Abutments
- K132844 – Straumann CARES Bone Level Screw-retained Bars, STRAUMANN CARES Bone Level Screw-retained Bridges
- K112280 – Straumann CARES Screw-retained Bridge Titanium, STRAUMANN CARES Dolder Bar Titanium
- K101465 – Straumann CARES Bridge; STRAUMANN CARES Dolder Bar
- K190097 – Straumann CARES Screw-retained Bridges and Bars
- K190662 – MRI Compatibility for Existing Straumann Dental Implant Systems
- K150938 – Straumann Dental Implant System – Roxolid SLA Implants
- K163194 – Neodent Implant System - GM Line
- K172798 – Straumann CARES Abutments CoCr

## 5.4 Device Description

TLX Dental Implant:

The TLX Dental Implant are fully tapered implants manufactured utilizing the Roxolid material and are finished with SLActive surface. The connection is identified as conical fitting with Torx style engaging feature. TLX implants are presented with 3 prosthetic platforms as listed below:

- NT (Narrow TorcFit)
- RT (Regular TorcFit)
- WT (Wide TorcFit)

The internal connection is identical for all prosthetic platforms, implant diameters, and implant lengths.

TLX Closure Caps and Healing Caps:

The closure caps are screwed into the implant to protect the inner configuration and shoulder of the implant during the healing phase in cases of submerged (submucosal) healing protocols. The healing caps are screwed into the implant to protect the inner configuration of the implant in cases of transmucosal healing protocols. They are placed out of occlusion and do not support a prosthetic restoration. Closure caps and healing caps are used during the healing phase only.

The TLX Closure Caps and Healing Caps are manufactured from Titanium Grade 4 and are laser marked with NT, RT or WT for identification purposes. They are provided sterile and are available in different heights and diameters.

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.

The TLX Temporary Abutments are manufactured from TAN and consist of a coronal section, a platform and a connection part. The abutments are provided non-sterile with instructions for end user sterilization. The Temporary Abutments are seated in the implant with a basal screw which is also manufactured from TAN and are laser marked with NT, RT or WT for identification purposes. The Basal screw is delivered with the abutment. The TLX Temporary Abutments are available for Crown and Bridge/Bar restorations.

TLX Variobase for Crown

The TLX Variobase for Crown incorporates the implant to abutment connection (TorcFit) and is available for each of the three implant diameter platforms (NT, RT & WT) with a different abutment chimney height and prosthetic platform diameter. The TLX Variobase Abutments for Crown are titanium bases to be used as the lower part of two-piece abutments. The upper part of the two-piece abutment is a CAD/CAM designed and manufactured restoration. These components, which once assembled together and placed with the corresponding basal screw, constitute the final medical device.

TLX Variobase for Crown will be marketed as stand-alone component or through the CARES® X-Stream workflow. In the latter the prosthetic restoration is designed though CARES® Visual

software (Digital CARES workflow) and manufactured in a validated Straumann milling center. The prosthetic restoration is then shipped together with the TLX Variobase for Crown and the Basal screw.

All digitally designed copings and/or crowns for use with the TLX Variobase for Crown are intended to be sent to Straumann for manufacture at a validated milling center.

The TLX Variobase for Crown is provided non-sterile with instructions for end user steam sterilization.

Prosthetic Restoration Design and Materials

The following materials are available within the digital workflow for the manufacturing of prosthetic restorations:

Final restorations:

- zerion® LT
- zerion® ML
- zerion® UTML
- IPS e.max CAD
- coron®

Temporary restoration:

- polycon® ae

TLX CARES Abutment TAN

The TLX CARES Abutments TAN are packed and delivered with the Basel screw. Both are manufactured from TAN (titanium-aluminum-niobium alloy/ Ti-6Al-7Nb).

TLX CARES Abutments TAN are intended to be placed into Straumann implants to provide support for prosthetic reconstructions such as crowns and bridges.

The final abutment, fabricated from a pre-milled blank, is designed to allow for individual customization regarding function and esthetics.

The pre-milled blank incorporates the pre-milled implant to abutment connection (TorcFit) and has a cylindrical body with enough material volume to create a wide range of geometries for the final abutment.

The TLX CARES Abutments TAN is available for each of the three implant platforms.

Inside the abutment, a screw channel provides access to the internal thread feature of the implant, such that the component can be firmly attached while providing fit between screw, abutment and implant.

The design of the customized abutment must be made using the validated Straumann CARES Visual software (Digital CARES workflow).

Finally, the design file is transferred digitally to a Straumann validated milling center.

The TLX CARES Abutment TAN is provided non-sterile with instructions for end user steam sterilization.

TLX Screw-retained Bridges and Bars:

The Straumann CARES Screw-retained Bridges and Bars, also referred to as SRBB are packed and delivered with the corresponding basal screws.

SRBB devices are manufacture from either

- Titanium Grade 4 or
- Cobalt chromium (also referred to as CoCr (or coron).
- the Basal Screw is manufactured from TAN (titanium-aluminum-niobium alloy/ Ti-6Al-7Nb).

SRBB are used for the restoration of Straumann dental implants with different endosteal diameters, lengths and platforms.

- CARES bars are to be combined with an overdenture to treat edentulous cases.
- CARES fixed bars are superstructures for the direct application with dental resin and prefabricated teeth to treat edentulous cases.
- CARES Screw-retained Bridges are intended to be directly veneered with dental veneering ceramics.

The purpose of this premarket notification is to expand the currently cleared abutment-to-implant interfaces to include the TLX implant system.

The SRBB devices are available for each of the three prosthetic platforms (NT, RT, WT).

The design of the SRBB devices must be made using the validated Straumann CARES Visual software (Digital CARES workflow).

Finally, the design file is transferred digitally to a Straumann validated milling center.

The TLX SRBB are provided non-sterile with instructions for end user steam sterilization.

TLX Basal screw

The Basal screw is used to seat the temporary abutments, the TLX Variobase Abutments or the TLX Screw-retained Bridges and Bars to the dental implant and can be also be used during lab procedures to fix lab prosthetic parts on implant analogs. They are provided along the prosthetic components, but they are also provided as standalone screws. The TLX basal screws is manufactured from TAN.

## 5.5 Indications for Use

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 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).

## 5.6 Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in Table 1 through Table 6. Regarding the technological characteristics of the Implants described in Table 1, the following describes the relevant equivalence discussion:

- K150938 was introduced for comparison between the subject Ø3.75 x 6 mm and the reference Ø4.1 x 6 mm implant. In order to address the difference in the diameter/thread design, surface area comparison as well as pull-out strength were conducted to demonstrate equivalence.
- K163194 was introduced for comparison between the subject Ø5.0 x 18 mm and the reference Ø5.0 x 18 mm implant.
- K171784 and K150938 were introduced for comparison of the implant neck shape.

# K200586 – Traditional 510(k)

## Straumann® TLX Implant System

### Substantial Equivalence Discussion

| Feature | Proposed Device | Primary Predicate Device | Reference Device | Reference Device | Reference Device | Reference Device |
|---|---|---|---|---|---|---|
| | **K200586 Straumann TLX Implant System** | **K173961 Straumann BLX Implant System** | **K181703 Straumann® BLX Line Extension** | **K171784 Straumann Dental implant system** | **K150938 Roxolid SLA Implants** | **K163194 Neodent Implant System - GM Line** |
| **Indications for Use** | 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® 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. | 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® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and 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® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and 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). | The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. |
| **Material** | Titanium-13 Zirconium alloy (Roxolid®) | Titanium-13 Zirconium alloy (Roxolid®) | Titanium-13 Zirconium alloy (Roxolid®) | Titanium-13 Zirconium alloy (Roxolid®) | Titanium-13 Zirconium alloy (Roxolid®) | Titanium grade 4 |

# K200586 – Traditional 510(k)

## Straumann® TLX Implant System

### Substantial Equivalence Discussion

| Feature | Proposed Device | Primary Predicate Device | Reference Device | Reference Device | Reference Device | Reference Device |
|---|---|---|---|---|---|---|
| | **K200586 Straumann TLX Implant System** | **K173961 Straumann BLX Implant System** | **K181703 Straumann® BLX Line Extension** | **K171784 Straumann Dental implant system** | **K150938 Roxolid SLA Implants** | **K163194 Neodent Implant System - GM Line** |
| **Surface Treatment** | Hydrophilic SLActive® | Hydrophilic SLActive® | Hydrophilic SLActive® | Hydrophilic SLActive® | SLA | Neoporos<br>Acqua |
| **Implant to Abutment Connection** | TorcFit<br>(with conical fitting) | TorcFit<br>(with conical fitting) | TorcFit<br>(with conical fitting) | Narrow CrossFit (NC)<br>Regular CrossFit (RC)<br>Regular Neck (RN)<br>Wide Neck (WN) | Narrow CrossFit (NC)<br>Regular CrossFit (RC)<br>Narrow Neck CrossFit (NNC)<br>Regular Neck (RN)<br>Wide Neck (WN) | GM interface; 16° Morse taper with anti-rotational features. |
| **Implant Diameter** | Ø3.75, 4.0, 4.5, 5.0, 5.5, and 6.5 mm | Ø4.5, 5.5, and 6.5 mm | Ø3.75 mm | Ø3.3, 4.1, and 4.8 mm | Ø3.3, 4.1, and 4.8 mm | Ø 3.5 to 5.0 mm |
| **Implant Length** | Ø3.75, 4.0, 4.5, 5.0 mm:<br>6, 8, 10, 12, 14, 16 and 18 mm<br>Ø5.5 and 6.5 mm:<br>6, 8, 10, 12 mm | 6 to 18 mm | 8 to 18 mm | 6 to 18 mm | 6, 8, 10, 12, 14, 16 mm | 8 to 18 mm |
| **Implant Design** | Tapered body | Tapered body | Tapered body | Parallel wall and bone level tapered (BLT) | Parallel wall and bone level tapered (BLT) | Titamax<br>Helix<br>Drive |
| **Implant neck** | Tulip shape | n/a (bone level) | n/a (bone level) | Tulip shape<br>n/a (bone level) | Tulip shape<br>n/a (bone level) | n/a (bone level) |
| **Prosthetic platforms** | NT, RT, and WT | RB and WB | RB and WB | RN, WN, RC, and NC | NC, RC, NNC, RN, and WN | GM interface |
| **Thread Pitch** | 1.7, 2.0, 2.1, 2.2, 2.5, 2.6, and 2.8 mm | 2.0 to 2.8 mm | 1.7 to 2.6 mm | 0.8 and 1.25 mm | 0.8 and 1.25 mm | Titamax<br>Helix<br>Drive |
| **Sterilization Method** | Irradiation | Irradiation | Irradiation | Irradiation | Irradiation | Irradiation |

**Table 1 – Comparison of subject device versus primary predicate device - TLX Dental Implant**

| Feature | Proposed Device | Primary Predicate Device |
|---|---|---|
| | **K200586** | **K173961** |
| **Indications for Use** | 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. | Straumann® Closure Caps and Healing Abutments 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 shape, maintain and stabilize the soft tissue during the healing process. Closure caps and healing abutments should be used only with suitable implant connections. Straumann Closure Caps and Healing Abutments have a maximum duration of usage of 6 months. |
| **Material** | Titanium Grade 4 | Titanium Grade 4 |
| **Surface** | No treatment | Anodized |
| **Implant to Abutment Connection** | NT, RT, and WT | RB/WB and WB |
| **Diameter or Minor Oval Dimension/ Major Oval Dimension** | Closure caps:<br>Ø2.7, 4.0, and 5.5 mm<br><br>Healing caps:<br>Ø4.0, 5.5, and 7.2 mm | Closure caps:<br>Ø3.4 and 4.5 mm<br><br>Healing abutments:<br>Ø4.0, 5.0, 6.0, 6.5, and 7.5 mm |
| **Overall Length** | Closure caps:<br>4.4, 5.2, and 5.4 mm<br><br>Healing caps:<br>5.5 to 8.2 mm | Closure caps:<br>4.6 and 4.7 mm<br><br>Healing abutments:<br>6.8 to 11.9 mm |
| **Gingival Heights** | Closure caps:<br>0.5 and 1.5 mm<br><br>Healing abutments:<br>2.0, 3.0 and 4.5 mm | Closure caps:<br>0.4 and 0.5 mm<br><br>Healing abutments:<br>1.5 to 3.5 mm |
| **Sterilization Method** | Irradiation | Irradiation |

**Table 2 – Comparison of subject device versus reference predicate device - TLX Closure Caps and Healing Caps**

| Feature | Proposed Device | Primary Predicate Device |
|---|---|---|
| | K200586 | K173961 |
| **Indications for Use** | 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.<br>TLX Temporary Abutments have a maximum duration of usage of 180 days. | Straumann® BLX Basal Screws and Temporary Abutments<br>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.<br>BLX Temporary Abutments have a maximum duration of usage of 180 days. |
| **Material** | Ti-6Al-7Nb | Ti-6Al-7Nb |
| **Implant to Abutment Connection** | TorcFit | TorcFit |
| **Implant to Abutment Connection** | NT, RT & WT | RB/WB & WB |
| **Diameter abutment** | Ø3.90, 5.05, and 7.00 mm | Ø3.8, 4.5, 5.5 and 6 mm |
| **Gingival Heights** | n/a | 0.75, 1.5, 2.5 and 3.5 mm |
| **Chimney Heights** | 10 mm | 10 mm |
| **Sterilization Method** | Non-sterile/<br>End user sterilized | Non-sterile/<br>End user sterilized |
| **Surface** | No treatment | Anodized |

**Table 3 – Comparison of subject device versus reference predicate device – TLX Temporary Abutment**

# K200586 – Traditional 510(k)

## Straumann® TLX Implant System

### Substantial Equivalence Discussion

| Feature | Proposed Device | Primary Predicate Device | Reference Device |
|---|---|---|---|
| | K200586 | K173961 | K190082 |
| **Indications for Use** | Straumann® Variobase® prosthetic components directly connected to the endosseous dental implant are in-tended 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. | Straumann® Variobase® prosthetic components directly or indirectly 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. | Straumann® Variobase® prosthetic components directly or indirectly 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. |
| **Material** | TAN (Titanium-Aluminum-Niobium alloy/Ti-6Al-7Nb) | TAN (Titanium-Aluminum-Niobium alloy/Ti-6Al-7Nb) | TAN (Titanium-Aluminum-Niobium alloy/Ti-6Al-7Nb) |
| **Implant to Abutment Connection** | TorcFit | TorcFit | TorcFit |
| **Implant to Abutment Connection** | NT, RT, and WT | RB/WB and WB | RB/WB and WB |
| **Prosthetic Platform Diameter Ø (mm)** | 4.0 (NT), 5.0 (RT) and 7.0 (WT) | 3.8 (RB/WB), 4.5 (RB/WB), and 5.5 (WB) | 3.8 (RB/WB), 4.5 (RB/WB), and 5.5 (WB) |
| **Abutment Chimney Heights (mm)** | 5.5 (NT), 6.0 (RT) and 6.5 (WT) can be reduced by up to 2 mm until<br>5.5 (NT)→3.5<br>6.0 (RT) →4.0<br>and 6.5 (WT) →4.5 | 5.5 mm (can be reduced up to 2 mm until 3.5mm) | 5.5 mm (can be reduced up to 3.5 mm) |
| **Digital Coping/ Crown Material and CAD design limits: Minimum wall thickness (mm)** | <u>Final restorations</u><br>zerion® LT: 0.4<br>zerion® ML: 0.4<br>zerion® UTML: 0.5<br>IPS e.max CAD:0.7<br>Coron®: 0.3<br><br><u>Temporary restoration</u><br>polycon® ae: 0.7 | <u>Final restorations</u><br>IPS e. max CAD:0.7<br><br><u>Temporary restoration</u><br>Polycon ® ae: 0.5 | <u>Final restorations</u><br>coron®: 0.3<br>zerion® LT: 0.4<br>zerion®ML: 0.4<br>zerion® UTML: 0.5 |
| **CAD design limits: Coping crown angulation** | Up to 30° | Up to 30° | Up to 30° |

| Feature | Proposed Device | Primary Predicate Device | Reference Device |
|---|---|---|---|
| | K200586 | K173961 | K190082 |
| **Minimum Abutment Post Height (after two-piece abutment assembly)** | 4.0 mm | 4.0 mm | 4.0 mm |
| **Design Workflow** | Digital CARES workflow (CAD) | Wax-up or Straumann CARES® Visual, Dental Wings software using the Straumann CARES Visual Plug-In and 3Shape | Wax-up or Straumann CARES® Visual, Dental Wings software using the Straumann CARES Visual Plug-In and 3Shape |
| **Manufacturing Workflow** | Straumann Milling | Straumann Milling | Straumann Milling |
| **Sterilization Method** | Non-sterile/ End user sterilized | Non-sterile/ End user sterilized | Non-sterile/ End user sterilized |
| **Surface** | Not anodized | Partially anodized | Partially anodized |
| **Mode of Action** | Screw-retained or cement retained | Screw-retained or cement retained | Screw-retained or cement retained |

**Table 4 – Comparison of subject device versus reference predicate device – TLX Variobase for Crown**

| Feature | Proposed Device | Reference Device | Reference Device |
|---|---|---|---|
| | K200586 | K190040 | K172798 |
| **Indications for Use** | Straumann® CARES® Abutments TAN are indicated for single-tooth replacements and multiple-tooth restorations. The prosthetic restoration can be cement-retained. | The Straumann CARES Abutments are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/Screw-retained. | The Straumann® CARES® Abutments CoCr are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw-retained. |
| **Material** | TAN | TAN<br>CoCr | CoCr |
| **Implant to Abutment Connection** | TorcFit | TorcFit | synOcta and CrossFit |
| **Implant to Abutment Connection** | NT, RT, and WT | RB/WB and WB | RN, WN, NC, and RC |
| **Type of recommended restoration** | Crowns and bridges | Crowns and bridges | Crowns and bridges |
| **Design workflow** | Digital CARES workflow (CAD) | Wax-up or Straumann CARES Visual, Dental Wings software using the Straumann CARES Visual Plug-In | Digital CARES workflow (CAD) |
| **Manufacturing workflow** | Digital CARES workflow via Straumann milling center | Digital workflow via Straumann milling center | Digital CARES workflow via Straumann milling center |
| **CAD design limits: Coping/crown angulation** | Up to 30° | Up to 30° | Up to 30° |
| **CAD design limits: Minimum wall thickness (mm)** | 0.33 | 0.33 | 0.33 |
| **CAD design limits: Minimum abutment post height (mm)** | 4 mm | N/A | N/A |
| **Sterilization method** | Non-sterile/<br>End user sterilized<br>(steam autoclave) | Non-sterile/<br>End user sterilized<br>(steam autoclave) | Non-sterile/<br>End user sterilized<br>(steam autoclave) |
| **Mode of action** | Screw-retained | Screw-retained | Screw-retained |

**Table 5 – Comparison of subject device versus reference predicate device - TLX CARES Abutment TAN**

| Feature | Proposed Device | Reference Device |
|---|---|---|
| | **K200586** | **K190097** |
| **Indications for Use** | Straumann® CARES® Screw-retained Bridges and Bars are indicated for use as bars and bridges that attach to 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). | Straumann® CARES® Screw-retained Bridges and Bars are indicated for use as bars and bridges that attach to 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), and BLX implants of the Straumann Dental Implant System (SDIS). |
| **Material** | SRBB Restoration:<br>Cobalt Chrome Alloy (CoCr)<br>Titanium Grade 4<br>Screw:<br>TAN (Titanium-Aluminum-Niobium alloy/Ti-6Al-7Nb) | Restorations:<br>Cobalt Chrome Alloy (CoCr)<br>Titanium Grade 4<br>Screws:<br>Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb) |
| **Implant to SRBB Connection (interface)** | Bone Level (BL) - external cone<br>Tissue Level (TL) - internal cone<br>BLX - internal cone<br>TLX - internal cone | Bone Level (BL) - external cone<br>Tissue Level (TL) - internal cone<br>BLX - internal cone |
| **Supported Straumann Interfaces** | Bone Level – RC, NC<br>Tissue Level – RN, WN<br>BLX – RB, WB<br>TLX – NT, RT, WT | Bone Level – RC, NC<br>Tissue Level – RN, WN<br>BLX – RB, WB |
| **Restoration Types Supported** | Bridges from 2 units to 16 units (full-arch)<br>Bars from 2 units to 10 units | Bridges from 2 units to 16 units (full-arch)<br>Bars from 2 units to 10 units |
| **Design Workflow** | Digital CARES workflow (CAD) | CAD |
| **Design Software** | Straumann CARES Visual | Straumann CARES Visual |
| **Manufacturing Workflow** | Digital CARES workflow via Straumann milling center | Digital CARES workflow via Straumann milling center |
| **Design Limits for Bridges** | Critical geometry parameters are enforced by CARES Visual limits | Critical geometry parameters are enforced by CARES Visual limits |
| **Design Limits for Bars** | Critical geometry parameters are enforced by CARES Visual limits | Critical geometry parameters are enforced by CARES Visual limits |
| **Sterilization method** | Non-sterile/<br>End user sterilized (steam autoclave) | Non-sterile/<br>End user sterilized (steam autoclave) |
| **Mode of Action** | Screw-retained | Screw-retained |

**Table 6 – Comparison of subject device versus reference predicate device - TLX Screw-retained Bridges and Bars (SRBB)**

## 5.7 Performance Testing

### 5.7.1 Bench Testing

Dynamic fatigue 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 the TLX Dental Implant system is equivalent to the predicate and reference devices. The tests were conducted in both, saline (2 Hz and 37°C) and air (15 Hz). In saline at 2 million cycles for permanent and 200,000 cycles for temporary restorations. In air at 5 million cycles for permanent and 500,000 cycles for temporary restorations.

Surface area comparison and pull-out testing were performed on the Ø3.75 x 6 mm NT implants and were determined to have a larger endosseous surface area and higher pull-out force compared to the reference Ø4.1 x 6 mm device.

### 5.7.2 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.

### 5.7.3 Sterilization Validation and Packaging

The sterilization process for the TLX Dental Implant system as recommended in the labeling was validated according to:

For devices delivered sterile (TLX implants and Healing/Closure caps) - a sterility assurance level (SAL) of $10^{-6}$ had been validated 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 all TLX devices 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.

For devices delivered non-sterile to be end-user sterilized (TLX Temporary abutments, Variobase for Crown, CARES Abutment TAN and Screw-retained Bridges and Bars), The recommended sterilization has been validated according to ISO 17665-1 and ISO 17665-2 and to applicable recommendations in the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015". There are no changes to the sterilization procedures or processes from those of the Straumann predicate devices.

### 5.7.4 Software Validation

Software validation testing were conducted and documentation was provided according to the FDA guidance documents "Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations" and "General Principles of Software Validation; Final Guidance for Industry and FDA Staff". The software for this device was considered as a "moderate" level of concern.

## 5.8 Conclusion

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