June 2, 2022

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

Re: K220751
Trade/Device Name: Straumann® BLX Temporary Abutment, VITA CAD-Temp, PMMA
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 11, 2022
Received: March 15, 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)*

K220751

Device Name:

Straumann® BLX Temporary Abutment, VITA CAD-Temp, PMMA

Indications for Use *(Describe)*

Straumann® temporary prosthetic components are indicated to be used prior to the insertion of the final components to maintain, stabilize, and shape the soft tissue during the healing phase. They must not be placed in occlusion. Straumann® temporary abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of partially edentulous patients with temporary crowns and bridges.

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 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:	Viviana Horhoiu Regulatory Affairs and Compliance manager Institut Straumann AG Phone number: +41 61 965 1512
Date of Submission:	May 30, 2022

5.2 Name of the Device

Trade Names:	Straumann® BLX Temporary Abutment, VITA CAD-Temp, PMMA
Common Name:	Endosseous dental implant abutment
Classification Name:	Endosseous dental implant abutment
Regulation Number:	§872.3630
Device Classification:	Class II
Product Code(s):	NHA
Classification Panel:	Dental

5.3 Predicate Device(s)

Primary Predicate:

- *K173961 – Straumann® BLX Implant System – Institut Straumann AG*

Reference Device:

- *K122192 – Straumann Temporary Abutments, PMMA – Institut Straumann AG*

5.4 Device Description

The subject temporary abutments will be marketed as Straumann® BLX Temporary Abutment, VITA CAD-Temp, PMMA, however, throughout this 510(k) Summary the subject devices will be referred to as BLX Temporary Abutment, PMMA.

Straumann® BLX Temporary Abutments PMMA are temporary abutments intended for placement on Straumann BLX Dental Implants with RB/WB and WB connection platforms. The temporary abutments are made of polymethyl methacrylate (PMMA), with a Titanium Alloy (TAN) inlay.

5.5 Indications for Use

Straumann® temporary prosthetic components are indicated to be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. They must not be placed in occlusion. Straumann® temporary abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of partially edentulous patients with temporary crowns and bridges.

5.6 Technological Characteristics

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number		**K173961**	**K122192**	
Indications for Use	Straumann® temporary prosthetic components are indicated to be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. They must not be placed in occlusion. Straumann® temporary abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of partially edentulous patients with temporary crowns and bridges.	**Straumann® BLX Basal Screws and Temporary Abutments** 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.	Straumann® temporary abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of partially edentulous patients with temporary crowns and bridges.	**Equivalent** The subject and primary predicate device indications for use statements are equivalent. The subject device does not contain language regarding final abutments and the subject device is for temporary use only. The type of prosthetic restorations is implied for the primary predicate device, but included specifically in the subject and reference device indications for use statements. The statement regarding the maximum duration of usage has been moved to the Instructions for Use for the subject devices.
Material	Titanium alloy/TAN (Ti-6Al-7Nb), PMMA	Titanium alloy/TAN (Ti-6Al-7Nb)	Titanium alloy/TAN (Ti-6Al-7Nb), PMMA	**Identical** The materials are identical to the reference device.
Implant to Abutment Connection	TorcFit®	TorcFit®	CrossFit® synOcta	**Identical** The connection is identical to the primary predicate device.

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number		**K173961**	**K122192**	
Compatibility	RB/WB and WB	RB/WB and WB	Narrow CrossFit® (NC) Regular CrossFit® (RC) Narrow Neck CrossFit® (NNC) Regular Neck (RN) Wide Neck (WN)	**Identical** The compatibility is identical to the primary predicate device.
Diameter or Minor Oval Dimension/ Major Oval Dimension	Major oval diameter: 10 mm Minor oval dimensions: 5 mm	RB/WB: Ø3.8, Ø4.5, Ø6.0 WB: Ø5.5	Major oval diameter: 10.1 mm Minor oval dimensions: 5 mm	**Equivalent** The diameters are nearly identical to the reference devices.
Overall abutment length	15.1 and 16.1 mm	13.5, 14.1, 15.1, 16.1, 17.1 mm	16.3 mm	**Identical** The overall abutment lengths are identical to two of the abutment lengths of the primary predicate device.
Gingival heights	1.5 mm	0.75, 1.5, 2.5 and 3.5 mm	1.0 mm	**Identical** The gingival height is identical to one of the gingival heights of the primary predicate device.
Prosthesis Fixation	Screw-retained	Screw-retained	Screw-retained	**Identical** The prosthetic fixation is identical to the primary predicate and reference devices.
Sterilization Method	Non-sterile	Non-sterile	Non-sterile	**Identical** The subject devices are provided non-sterile and require the same cleaning, disinfection and sterilization procedure as the primary predicate and reference devices.

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number		**K173961**	**K122192**	
Duration of Use	6 months	6 months	6 months	**Identical** The duration of use is identical for the subject, primary predicate, and reference devices.

Table 1 – Comparison of the subject devices with the primary predicate and reference devices

5.7 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 the BLX Temporary Abutments PMMA performed as well as the reference devices.

The subject device materials, PMMA and TAN (titanium alloy), are identical to the reference device materials. The manufacturing processes, packaging, body/fluid contact are identical to the reference devices; therefore, no new issues regarding biocompatibility were raised.

The sterilization validation for the BLX Temporary Abutments PMMA, 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"*, was leveraged from K162890.

5.8 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject devices, the BLX Temporary Abutments PMMA, are substantially equivalent to the legally marketed primary predicate and reference devices.