March 18, 2021

Institut Straumann AG
% Chanrasmey White
Regulatory Affairs Specialist
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01801

Re: K201681
Trade/Device Name: Straumann Immediate Temporary Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 12, 2021
Received: February 16, 2021

Dear Chanrasmey White:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201681

Device Name
Straumann® Immediate Temporary Abutments

Indications for Use *(Describe)*
The Straumann Immediate Temporary Abutment and associated Plastic Coping are indicated to be placed into Straumann dental implants (BL, BLT or BLX) to provide a support structure for a temporary aesthetic oral rehabilitation of partially edentulous patients with crowns. 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 for up to 180 days.
The Straumann Immediate Temporary Abutment and associated Plastic Coping must be placed out of occlusion.

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 K201681

5.1 Submitter

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

Phone Number: 978-747-2614

Fax Number: 978-747-0023

Contact Person: Chanrasmey White

Date of Prepared: March 17, 2021

5.2 Device

Trade Name: Straumann® Immediate Temporary Abutments

Common Name: Endosseous Dental Implant Abutments

Classification Name: Endosseous Dental Implant Abutments

Regulatory Class: II (21 CFR 872.3630)

Product Code: NHA (21 CFR 872.3630)

5.3 Predicate Device

Primary Predicate:

K122192 – Straumann Temporary Abutments, PMMA

Reference Predicate:

K192401 – Straumann Screw Retained Abutments

K181703 – BLX Implant System

K190662 – MRI Compatibility for Existing Straumann Dental Implant System

K041070 – Straumann Temporary Coping

5.4 Device Description

The Straumann Immediate Temporary Abutment and associated Plastic Coping consist of a titanium abutment and PMMA coping for the Straumann dental implants BL, BLT and BLX. The abutments are available in a variety of gingival heights and diameters to fit individual patient situations. The PMMA coping is compatible with the subject Immediate Temporary Abutments. The Straumann Immediate Temporary Abutment and associated Plastic Coping are indicated to provide a support structure for a temporary aesthetic oral rehabilitation of partially edentulous patients with crowns. 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 for up to 180 days.

5.5 Indications for Use

The Straumann Immediate Temporary Abutment and associated Plastic Coping are indicated to be placed into Straumann dental implants (BL, BLT or BLX) to provide a support structure for a temporary aesthetic oral rehabilitation of partially edentulous patients with crowns. 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 for up to 180 days.

The Straumann Immediate Temporary Abutment and associated Plastic Coping must be placed out of occlusion.

5.6 Technological Characteristics

The subject device is equivalent to the primary predicate and reference devices sharing the same material and fundamental operating principles. The differences in indications for use are addressed in performance testing provided in this submission demonstrating equivalent product performance. The subject and the primary predicate devices are intended to support temporary prosthetic reconstructions. The subject devices have a contact duration of up to 180 days compared to the primary predicate and reference devices, biocompatibility testing has been performed to support the 180 duration of use. The technological characteristics of the subject device are compared to the primary predicate and reference devices in Table 1 and Table 2. The subject devices are one-piece abutments opposed to the two-piece temporary abutments cleared per K122192. The one-piece design allows the abutment to be directly screwed into the

implant. The differences in technological differences are addressed in the performance testing provided in the submission which demonstrates equivalency in product performance.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	**Subject Device**	**K122192**	**K192401**	**K181703**
Indications for Use	The Straumann Immediate Temporary Abutment and associated Plastic Coping are indicated to be placed into Straumann dental implants (BL, BLT or BLX) to provide a support structure for a temporary aesthetic oral rehabilitation of partially edentulous patients with crowns. 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 for up to 180 days. The Straumann Immediate Temporary Abutment and associated Plastic Coping must be placed out of occlusion.	Straumann Temporary Abutments VITA CAD-Temp are indicated for use with Straumann Bone Level and Tissue Level implants for temporary crown and bridge restorations, and to maintain, stabilize and shape the soft tissue during the healing phase for up to six months, and should be placed out of occlusion.	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. Temporary Abutments have a maximum duration of usage of 180 days.	Straumann® BLX Implants 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® BLX SRAs and Anatomic 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.
Material	**Abutment:** Ti-6Al-7Nb **Plastic Coping:** Polymethyl Methacrylate (PMMA)	Ti-6Al-7Nb Polymethyl Methacrylate (PMMA)	Ti-6Al-7Nb	Ti-6Al-7Nb
Implant Compatibility	BL, BLT, BLX	BL, BLT, TL	BL, BLT	BLX

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	**Subject Device**	**K122192**	**K192401**	**K181703**
Abutment Diameter	Ø3.8 and 4.5	Ø5.0, 7.0, and 10.0 mm	Ø3.5 and 4.6 mm	Ø4.6 mm
Gingival Heights	BL and BLT - 1, 2, and 3 mm BLX – 1.5, 2.5, and 3.5 mm	1.0, 2.5, 4.0, and 5.5 mm	1.5, 2.5, 3.5, 4.5, and 5.5 mm	1.5, 2.5, 3.5, and 4.5 mm
Abutment Angulation	0°	0°	0, 17 and 30°	0, 17 and 30°
Indexing Type/ Presence	Non-Engaging	Engaging	Straight - Non-Engaging	Straight – Non-Engaging
Integrated Screw Technology	Yes Machined one-piece	No Coupled with a base screw	Yes – The straight abutments are machined one-piece	Yes – The straight abutments are machined one-piece
Restoration Type	Cemented	Cemented	Screw-retained	Screw-retained
Duration of Use	180 days	180 days	unlimited	unlimited
Sterilization	Sterile – Gamma Irradiation	Non-Sterile End User – Steam Autoclave	Sterile – Gamma Irradiation	Sterile – Gamma Irradiation
Loading	Single Unit	Single and Multi Unit	Single and Multi Unit	Single and Multi Unit

Table 1 – Immediate Temporary Abutment – Comparison Matrix

FEATURE	PROPOSED DEVICE	REFERENCE DEVICE
K Number	**Subject Device**	**K041070**
Indications for Use	The Straumann Immediate Temporary Abutment and associated Plastic Coping are indicated to be placed into Straumann dental implants (BL, BLT or BLX) to provide a support structure for a temporary aesthetic oral rehabilitation of partially edentulous patients with crowns. 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 for up to 180 days. The Straumann Immediate Temporary Abutment and associated Plastic Coping must be placed out of occlusion.	Temporary Copings are intended to serve as a base for temporary restorations.
Material	Polymethyl methacrylate (PMMA)	Polymethyl methacrylate (PMMA)
Restoration Type	Cemented	Cemented
Duration of Use	180 days	30 days
Sterilization	Non-Sterile Cleaned and disinfected	Non-Sterile

Table 2 – Plastic Coping – Comparison Matrix

5.7 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The subject devices have been assessed for biological safety 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 the subject device. The subject abutments are equivalent with regard to nature of body contact, duration of use, material formulation and sterilization methods compared to the primary and reference predicate devices and therefore, no new testing have been performed as biocompatibility is represented in the primary and reference predicate devices.

In support of the subject PMMA plastic copings, Cytotoxicity testing according to ISO 10993-5:2009, “Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity” and Chemical Analysis according to ISO 10993-18: 2020 “Chemical characterization of medical device materials within a risk management process” has been performed. In addition to the above testing a toxicology evaluation has been performed in support of the subject PMMA plastic copings. The test and evaluation performed confirmed the biocompatibility of the subject PMMA plastic copings.

Sterilization

The subject device are single patient devices. The Immediate Temporary Abutments will be delivered in a sterile packaging via Gamma Irradiation and the PMMA plastic coping will be delivered non-sterile. The PMMA plastic coping is to be manually cleaned and disinfected according to the Instructions for Use.

A sterilization validation assessment was performed according to ISO 11137 for the Immediate Temporary Abutments. The assessment concluded the proposed Immediate Temporary

Abutment can be adopted into the same sterilization process validated for the Straumann Sterile Prosthetics cleared for reference predicate K192401.

A high-level disinfectant validation was performed on the worst case PMMA device. The worst case was selected based on the most challenging designs for high level disinfection process due to size, surface, complexity and accessibility of the liquid solution. The subject PMMA Plastic Coping is not considered a new worst case and therefore can adopt the validation demonstrating the high-level disinfectant cleaning method can effectively disinfect the Plastic Coping.

The packaging of the Straumann® Immediate Temporary Abutments is identical to the packaging of the reference device K192401. There are no changes to the sterilization method or production process compared to the reference device. The shelf life for the proposed devices is 5 years identical to the reference device.

Bench Testing

The subject devices are MRI Conditional and do not introduce a new material or worst-case scenario and is represented under reference device K190662.

5.8 Conclusion

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