April 6, 2020

Straumann USA, LLC
Chanrasmey White
Regulatory Affairs Specialist
60 Minuteman Road
Andover, Massachusetts 01810

Re: K192401
Trade/Device Name: Straumann® Screw-Retained Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 5, 2020
Received: March 6, 2020

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,

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)*

K192401

Device Name

Straumann® Screw-Retained Abutments

Indications for Use *(Describe)*

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 are to be placed out of occlusion. Final abutments may be placed into occlusion for implants with sufficient primary stability or for implants that are fully osseointegrated.

Temporary Abutments have a maximum duration of usage of 180 days.

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

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 Submission: April 02, 2020

5.2 Device

Trade Name: Straumann® Screw-Retained 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:

- K181703 – BLX Implant System

Reference Predicate:

- K171757 – Straumann® Screw Retained Abutments
- K133421 – Straumann® Magellan™ Screw Retained Abutment System
- K190662 – MRI Compatibility for Existing Straumann Dental Implant Systems
- K072497 – NC Gold Abutment For Crowns

5.4 Device Description

The subject devices described in the submission are prosthetic components that are intended for use in prosthetic rehabilitations, directly or indirectly connected to the

endosseous dental implant. These devices are intended for use as an aid in prosthetic rehabilitations. The subject devices described in this submission are to be added Straumann's existing prosthetic portfolio.

5.4.1 Straumann® Screw-Retained Abutments

Straumann® Screw-Retained Abutments or SRAs include straight and angled (17° and 30°) abutments, basal screws and abutment carrier pin. The proposed Screw-Retained abutments are equivalent to the Screw-Retained Abutments cleared per K133421. The proposed Screw-Retained Abutments production processes are identical to Screw-Retained Abutments cleared per K171757. The new design of the straight Screw-Retained Abutment and smoothened angled Screw-Retained Abutments for Bone Level Implants are similar the Screw-Retained Abutments for BLX implants cleared per K181703.

5.4.2 Straumann® Temporary Copings

Straumann temporary copings are compatible with Straumann® Screw-Retained Abutments and are used for temporary restorations of single crowns and bridges. The copings are placed on dental abutments to support temporary prosthetic superstructures. 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 are to be placed out of occlusion. The temporary copings may be customized by the dentist to fit the oral situation and are then secured to a compatible abutment by screw fixation. The subject device is similar to the temporary copings cleared per K133421.

5.4.3 Straumann® Protective Cap

Straumann® Protective Caps are placed to the Straumann® Screw-Retained Abutments and intended to be used to protect the abutment configuration and maintain, stabilize and form the soft tissue during the healing process. The subject device is similar to the protective caps cleared per K133421.

5.5 Indications for Use

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 are to be placed out of occlusion. Final abutments may be placed into occlusion for implants with sufficient primary stability or for implants that are fully osseointegrated.

Temporary Abutments have a maximum duration of usage of 180 days.

5.6 Technological Characteristics

5.6.1 Straumann® Screw-Retained Abutments

The straight and smoothened angled Screw-Retained Abutments are made of Ti-6Al-7Nb (TAN) and designed to be used together with Straumann® Bone Level Implants having either NC (Narrow CrossFit) or RC (Regular CrossFit) connections. SRAs are laser engraved with either NC or RC to specify the implant type. SRAs are anodized blue for NC Ø3.5 mm and yellow for NC Ø4.6 mm. RC abutments are non-anodized. SRA straight abutments do not contain an anti-rotational feature, allowing the abutment to be screwed directly into the implant. Smoothened angled SRAs are connected to the implant by a basal screw. The proposed abutments will be delivered to the end user sterile via gamma irradiation.

The proposed Screw-Retained Abutments are equivalent to the Screw-Retained Abutments cleared per K133421 and K171757. The proposed Screw-Retained Abutments production processes are identical to screw-retained abutments cleared per K171757 with a new design. The new design, straight Screw-Retained Abutments and smoothened angled Screw-Retained Abutments for Bone Level Implants are similar in regards to design to the Screw-Retained Abutments for BLX cleared per K181703. Premarket notification K190662 is included as a reference device to address MRI compatibility. Premarket notification K072497 is included as a reference device for comparison of dynamic fatigue.

The technological characteristics of the proposed Screw Retained Abutments are compared to the primary and reference devices in Table 1.

5.6.2 Straumann® Temporary Copings for Screw-Retained Abutments

Temporary Copings are placed on dental abutments to support temporary prosthetic superstructures. Temporary copings in combination with the implant, abutment and temporary superstructure are used to restore function in patients missing a tooth or teeth for a temporary period. This commonly occurs during the healing and soft tissue management phase after implants are placed. Temporary restorations are not intended for receiving occlusal load from opposing dentition. This temporary solution to a missing tooth is later replaced by the final restoration.

The proposed temporary coping is designed for easier reworking at the dentist office. The proposed temporary coping will have a reduced wall thickness than temporary copings cleared per K133421.

The technological characteristics of the proposed Screw Retained Abutments are compared to the primary and reference devices in Table 2.

5.6.3 Straumann® Protective Caps for Screw-Retained Abutments

Protective caps are placed to the Screw-Retained Abutment and intended to be used to protect the abutment configuration and maintain, stabilize and form the soft tissue during the healing process. The proposed protective caps are made available with a width of 3.5 mm and 4.6 mm. The proposed protective caps are similar to the protective caps cleared per K133421 for Screw-Retained Abutments. The difference is a change in design from a columnar shape to a mushroom shape of the polymer body. The proposed protective caps are made out of PEEK and a screw made out of titanium alloy. The proposed protective caps are to be provided to the end user as non-sterile.

The technological characteristics of the proposed Screw Retained Abutments are compared to the primary and reference devices in Table 3.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	**Subject Device**	**K181703**	**K171757**	**K133421**
Indications for Use	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 are to be placed out of occlusion. Final abutments may be placed into occlusion for implants with sufficient primary stability or for implants that are fully osseointegrated. Temporary Abutments have a maximum duration of usage of 180 days.	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® Screw Retained Abutments are indicated to be placed into the implants of the Straumann® Dental Implant System to provide support for prosthetic reconstructions such as crowns, bridges and bars. The final processed devices have the purpose of restoring chewing function. Straumann® Screw Retained Abutments are indicated for screw-retained restorations.	Magellan™ abutments are indicated to be placed into dental implants to provide support for prosthetic reconstructions such as crown, bridges and bars. The final processed devices have the purpose of restoring chewing function.
Material	Ti-6Al-7Nb	Ti-6Al-7Nb	Ti-6Al-7Nb	Ti-6Al-7Nb
Implant to Abutment Connection	CrossFit® (NC and RC) (with conical fitting)	BLX (with conical fitting)	CrossFit® (NC and RC) (with conical fitting)	CrossFit® (NC and RC) (with conical fitting)
Restoration Type	Single and Multi (Straight NC GH 1.0 mm (ø 3.5 mm and ø4.6 mm), are indicated for single-crown restorations in central and lateral incisors, and for multi-unit restorations in incisors to pre-molars)	Single and Multi (Straight NC GH 1.0 mm (ø 3.5 mm and ø4.6 mm), are indicated for single-crown restorations in central and lateral incisors, and for multi-unit restorations in incisors to pre-molars)	Single and Multi (Straight NC GH 1.0 mm (ø 3.5 mm and ø4.6 mm), are indicated for single-crown restorations in central and lateral incisors, and for multi-unit restorations in incisors to pre-molars)	Single and Multi (Straight NC GH 1.0 mm (ø 3.5 mm and ø4.6 mm), are indicated for single-crown restorations in central and lateral incisors, and for multi-unit restorations in incisors to pre-molars)
Indexing type / presence	Straight – Non Engaging Angled – Engaging	Straight – Non Engaging Angled – Engaging	Engaging	Engaging
Surface Treatment / Anodization	3.5 NC Straight – Blue 4.6 NC Straight and Angled – Yellow 4.6 RC Straight and Angled - Grey	RB & WB - Magenta	3.5 NC Straight – Blue 4.6 NC Straight and Angled – Yellow 4.6 RC Straight and Angled - Grey	3.5 NC Straight – Blue 4.6 NC Straight and Angled – Yellow 4.6 RC Straight and Angled - Grey
Duration of Use	unlimited	unlimited	unlimited	unlimited
Platform Diameter	Ø3.5 and 4.6 mm	Ø4.6 mm	Ø3.5 and 4.6 mm	Ø3.5 and 4.6 mm
Gingival Heights	1.5, 2.5, 3.5, 4.5 and 5.5 mm	1.5, 2.5, 3.5 and 4.5 mm	1.0, 2.5, 4.0 and 5.5 mm	1.0, 2.5 and 4.0 mm

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	**Subject Device**	**K181703**	**K171757**	**K133421**
Angulation	0°, 17°, and 30°	0°, 17°, and 30°	0°, 17°, and 30°	0°, 17°, and 30°
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Non-sterile/ End user sterilized
Prosthesis Type	Screw-retained	Screw-retained	Screw-retained	Screw-retained
Sterilization	Sterile – Gamma Irradiation	Sterile – Gamma Irradiation	Sterile – Gamma Irradiation	Non-Sterile End User – Steam Autoclave

Table 1 – Comparison Matrix – Screw Retained Abutments

FEATURE	PROPOSED DEVICE	REFERENCE DEVICE
K Number	**Subject Device**	**K133421**
Indications for Use	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 are to be placed out of occlusion. Final abutments may be placed into occlusion for implants with sufficient primary stability or for implants that are fully osseointegrated. Temporary Abutments have a maximum duration of usage of 180 days.	Magellan™ abutments are indicated to be placed into dental implants to provide support for prosthetic reconstructions such as crown, bridges and bars. The final processed devices have the purpose of restoring chewing function.
Material	Ti-6Al-7Nb	Ti-6Al-7Nb
Abutment Connection	Crown – Engaging Bridges / Bars – Non Engaging	Crown – Engaging Bridges / Bars – Non Engaging
Temporary Coping Diameter	3.5 mm (NC) 4.6 mm (NC and RC)	3.5 mm (NC) 4.6 mm (NC and RC)
Temporary Coping Material	Ti-6Al-7Nb (TAN)	Titanium Grade 4
Duration	180 Days	Unlimited
Chimney Design **3.5 NC**	Inner Diameter: 2.3 Outer Diameter: 2.6	Inner Diameter 2.3 Outer Diameter 3.0
Chimney Design **4.6 NC and RC**	Inner Diameter: 2.3 Outer Diameter: 2.6	Inner Diameter: 2.3 Outer Diameter: 3.4
Temporary Coping Sterilization Method	Non-Sterile End User – Steam Autoclave	Non-Sterile End User – Steam Autoclave

Table 2 – Comparison Matrix – Temporary Copings

FEATURE	PROPOSED DEVICE	REFERENCE DEVICE
K Number	**Subject Device**	**K133421**
Indications for Use	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 are to be placed out of occlusion. Final abutments may be placed into occlusion for implants with sufficient primary stability or for implants that are fully osseointegrated. Temporary Abutments have a maximum duration of usage of 180 days.	Magellan™ abutments are indicated to be placed into dental implants to provide support for prosthetic reconstructions such as crown, bridges and bars. The final processed devices have the purpose of restoring chewing function.
Protective Cap Diameter	3.5 mm (NC) 4.6 mm (NC and RC)	3.5 mm (NC) 4.6 mm (NC and RC)
Protective Cap Height	5mm	5mm, 6.5mm and 8mm
Protective Cap Material	polyetheretherketone (PEEK) cap and Ti-6Al-7Nb (TAN) screw	polyetheretherketone (PEEK) cap and Ti-6Al-7Nb (TAN) screw
Shape	Mushroom design	Columnar design
Duration	180 days	180 days
Protective Cap Sterilization Method	Non-Sterile End User – Steam Autoclave	Non-Sterile End User – Steam Autoclave

Table 3 – Comparison Matrix – Protective Caps

5.7 Performance Data

The following performance data has been provided in support of the substantial equivalence determination. A summary is provided below.

5.7.1 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 assessment concluded the subject devices are equivalent in regards to nature of body contact, contact duration, material formulation and sterilization methods compared to the primary and reference predicate devices and therefore no new testing has been performed.

5.7.2 Sterilization

The Screw-Retained Abutments are provided to the end user as sterile via gamma irradiation. The proposed Screw-Retained Abutments production process are identical to the screw-retained abutments cleared per K171757. A sterilization validation assessment was performed according to ISO 11137. The assessment concluded the proposed Screw-Retained Abutments can be adopted into the same sterilization process validated for the Screw-Retained Abutments cleared per K171757.

The packaging of the Straumann® Screw-Retained Abutments is identical to the packaging of the reference devices cleared per K171757. There are no changes to the sterilization method or production process compared to the reference devices. The shelf life for the proposed Screw-Retained Abutments will remain 5 years.

5.7.3 Bench Testing

Dynamic fatigue, static strength, and torque 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 Straumann Screw-retained Abutments is equivalent to the predicate and reference devices.

Dynamic fatigue (and static strength) tests were performed to evaluate the fatigue load limits of the proposed Straumann Screw-retained Abutments. Based on worst-case considerations, both platforms straight and angled abutments were tested and shown to be equivalent to the reference predicate device K072497.

5.7.4 Clinical data

No device specific clinical data has been submitted to demonstrate substantial equivalence.

5.8 Conclusion

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