Straumann USA, LLC (on behalf of Institut Straumann AG)
% Jennifer M. Jackson, MS
Director, Regulatory Affairs & Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

November 27, 2017

Re: K171757
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: October 25, 2017
Received: October 26, 2017

Dear Jennifer M. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171757

Device Name
Straumann® Screw Retained Abutments

Indications for Use *(Describe)*

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: 1-978-747-2614

Fax Number: 1-978-747-0041

Contact Person: Chanrasmey White

Date of Submission: 10/25/2017

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:

- (K133421) Straumann® Magellan™ Screw Retained Abutment System

Reference Predicate:

- (K141871) Straumann Bone Level NC Angled Screw Retained Abutments
- (K151247) Straumann Screw Retained Abutments
- (K150814) Straumann Screw-Retained Abutment
- (K130808) Straumann Healing Abutments, Healing Caps, Closure Screws

5.4 Device Description

Straumann® Screw Retained Abutments include one-piece straight and angled (17° and 30°) abutments, basal screws and abutment carrier pin. The subject device is identical to the primary predicate, K133421, and subsequent premarket notification submissions K141871, K150814 and K151247 with the exception that the subject device will be delivered to the user sterile as opposed to non-sterile and a change in packaging to ensure sterility of the devices.

5.5 Indications for Use

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.

5.6 Technological Characteristics

The proposed Straumann® Screw Retained Abutments intended use, material, fundamental operating principles and overall design are identical to the primary predicate device. The subject device is identical to the primary predicate, K133421, and subsequent premarket notification submissions K141871, K150814 and K151247 with the exception that the subject device will be delivered to the user sterile as opposed to non-sterile and a change in packaging to ensure sterility of the devices. Packaging materials and configuration is equivalent to reference predicate device, Straumann® Straumann Healing Abutments, Healing Caps, Closure Screws, K130808. The technological characteristics of the subject devices are compared to the non-sterile predicate devices (K133421, K141871, K150814 and K151247) in the following table.

Feature	Subject Device	Primary PREDICATE Device	Reference DEVICE	Reference DEVICE	Reference DEVICE
K Number		**K133421**	**K141871**	**K150814**	**K151247**
Indication	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.	Straumann® Magellan ™ 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.	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.	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.	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.
Implant-to-Abutment Connection	Narrow CrossFit (NC) Regular CrossFit (RC)	Narrow CrossFit (NC) Regular CrossFit (RC)	Narrow CrossFit (NC)	Narrow CrossFit (NC)	Narrow CrossFit (NC) Regular CrossFit (RC)
Interface Type	Engaging	Engaging	Engaging	Engaging	Engaging
Platform Diameter(s)	NC Straight and Angled:	NC Straight:	NC Angled: Ø3.5 mm, Ø4.6 mm	NC Straight: Ø3.5 mm, Ø4.6 mm	NC Angled: Ø3.5 mm, Ø4.6 mm RC Angled:

Feature	Subject Device	Primary PREDICATE Device	Reference DEVICE	Reference DEVICE	Reference DEVICE
K Number		**K133421**	**K141871**	**K150814**	**K151247**
	Ø3.5 mm, Ø4.6 mm RC Straight and Angled: Ø4.6 mm	Ø3.5 mm, Ø4.6 mm RC Straight and Angled: Ø4.6 mm			Ø4.6 mm
Abutment Angulation(s)	0°, 17°, 30°	0°, 17°, 30°	17°, 30°	0°	17°, 30°
Gingival Height(s)	NC and RC Straight: 1.0, 2.5 and 4.0 mm NC and RC Angled: 2.5, 4.0 and 5.5 mm	NC and RC Straight: 1.0, 2.5 and 4.0 mm RC Angled: 2.5 and 4.0 mm	NC Angled: 2.5 and 4.0 mm	NC Straight: 1.0 mm	NC and RC Angled: 5.5 mm
Orientation of Angulation to Engagement Features	Type A (45°), Type B (0°)	Type A (45°), Type B (0°)	Type A (45°), Type B (0°)	N/A	Type A (45°), Type B (0°)
Device Material	Ti-6Al-7Nb titanium alloy	Ti-6Al-7Nb titanium alloy	Ti-6Al-7Nb titanium alloy	Ti-6Al-7Nb titanium alloy	Ti-6Al-7Nb titanium alloy
Sterilization	End user receives product sterilized per Gamma Irradiation, 25 kGy minimum Validated per ISO 11137-1 and ISO 11137-2 to an SAL of 10 x 10^{-6}	End user to sterilize product per IFU Method: Autoclave moist heat fractionated vacuum or gravity displacement Conditions: 134°C (273°F) for 5 minutes	End user to sterilize product per IFU Method: Autoclave moist heat fractionated vacuum or gravity displacement Conditions: 134°C (273°F) for 5 minutes	End user to sterilize product per IFU Method: Autoclave moist heat fractionated vacuum or gravity displacement Conditions: 134°C (273°F) for 5 minutes	End user to sterilize product per IFU Method: Autoclave moist heat fractionated vacuum or gravity displacement Conditions: 134°C (273°F) for 5 minutes

Table 1: Comparison of Subject Devices to non-sterile Predicates