DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 10, 2015

Straumann USA, LLC
Christopher Klaczyk
Director of Regulatory Affairs and Clinical Research
60 Minuteman Road
Andover, Massachusetts 01810

Re: K151247
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: July 10, 2015
Received: July 13, 2015

Dear Mr. Christopher Klaczyk:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
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)*
K151247

Device Name

Straumann® Screw Retained Abutments

Indications for Use *(Describe)*

The Straumann® Screw Retained Abutments are indicated to be placed into the NC and RC Bone Level 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.

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K151247

510(k) Summary

Submitter: Straumann USA, LLC (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810
Registration No.: 1222315 Owner/Operator No.: 9005052

Contact Person: Christopher Klaczyk
Director of Regulatory Affairs and Clinical Research

Date Prepared: August 9, 2015

Product Code(s): NHA (21 CFR 872.3630)

Device Class: II (21 CFR 872.3630)

Classification Panel: Dental

Classification Name: Endosseous dental abutment (21 CFR 872.3630)

Proprietary Name: Straumann® Screw Retained Abutments

Predicate Device(s):
- K133421, Straumann® Magellan Abutment System Primary Predicate
- K141871, NC Angled Screw Retained Abutments Reference Predicate

Device Description: The proposed Bone Level Screw Retained Abutments are a line extension of the Screw Retained Abutments previously cleared to market per K133421 and K141871. The proposed Screw Retained Abutment devices include one-piece straight and angled (17º and 30º) abutments, having a gingival height of 5.5 mm.

Indications For Use: The Straumann® Screw Retained Abutments are indicated to be placed into the NC and RC Bone Level 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.

Intended Use: Straumann abutments are intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns and bridges.

Materials: The subject devices are produced from titanium-6aluminum-7niobium alloy (TAN) conforming to ISO 5832-11. This is the same material as for the predicate devices previously cleared to market per premarket notification submissions K133421 and K141871.

Technological Characteristics: The proposed Straumann® Screw Retained Abutments are manufactured using precision machining systems from solid material (i.e. one-piece construction). All technological characteristics of the subject devices are the same as for predicate devices as shown in the table below.

Feature	Subject Devices NC & RC Screw Retained Abutments	Predicate Devices Screw Retained Abutments (K133421, K141871)
Implant-to-Abutment Connection	Narrow Cross Fit (NC) Regular Cross Fit (RC)	Narrow Cross Fit (NC) Regular Cross Fit (RC)
Platform Diameter(s)	NC: Ø4.6 mm RC: Ø4.6 mm	NC: Ø3.5 mm, Ø4.6 mm RC: Ø4.6 mm
Abutment Angulation(s)	NC: 17°, 30° RC: 17°, 30°	NC: 0°, 17°, 30° RC: 0°, 17°, 30°
Gingival Height(s)	NC: 5.5 mm RC: 5.5 mm	NC: 1.0, 2.5 and 4.0 mm RC: 1.0, 2.5 and 4.0 mm
Orientation of Angulation to Engagement Features	NC: Type A (45°), Type B (0°) RC: Type A (45°), Type B (0°)	NC: Type A (45°), Type B (0°) RC: Type A (45°), Type B (0°)
Material	Ti-6Al-7Nb titanium alloy	Ti-6Al-7Nb titanium alloy
Primary Package	Medical grade polyethylene blister with a sealing lid	Medical grade polyethylene blister with a sealing lid
Sterilization	Non-sterile; intended for terminal sterilization via moist heat (autoclave)	Non-sterile; intended for terminal sterilization via moist heat (autoclave)

Performance Data: Per *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments* dated May 12, 2004, the substantial equivalence of the subject device(s) are satisfactorily addressed via bench studies. Dynamic fatigue test data consistent with FDA guidance and ISO 14801 have been referenced in support of this submission.

Conclusions: Based upon our assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate devices.