DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 23, 2016

Institut Straumann AG
c/o Ms. Jennifer Jackson, M.S.
Head of Regulatory Affairs and Quality
Straumann USA, Inc.
60 Minuteman Road
Andover, Massachusetts 01810

Re: K153758
Trade/Device Name: Straumann® Bone Level Tapered Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 29, 2015
Received: December 30, 2015

Dear Ms. 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.

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,

for 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)*
K153758

Device Name

Straumann® Bone Level Tapered Implants

Indications for Use *(Describe)*

Straumann® Bone Level Tapered Implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann Bone Level Tapered Implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments).

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 K153758

Submitter: Straumann USA, LLC (on behalf of Institut Straumann AG)
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Prepared By: Christopher Klaczyk
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Date Prepared: March 7, 2016

Product Code(s): DZE (21 CFR 872.3640)

Device Class: II (21 CFR 872.3640)

Classification Panel: Dental

Classification Name: Endosseous dental implant (21 CFR 872.3640)

Proprietary Name: Straumann® Bone Level Tapered Implant

Predicate Device:: Straumann Bone Level Tapered Implants (K140878)

Reference Device(s): Straumann Roxolid SLA Implants (K150938)
Neodent CM Drive Line Extension (K150182)

Device Description: The subject devices represent a line extension of the previously cleared Bone Level Tapered Implants of the Straumann Dental Implant System (K140878 and K150938). The subject devices have the same diameters (3.3, 4.1 and 4.8 mm), the same implant-to-abutment interfaces (NC, RC), the same material (Ti-13Zr) and the same surface finishes (SLA, SLActive) as the identified primary predicate devices. The subject devices differ in that the lengths are 18 mm versus a maximum length for the primary predicate devices of 16 mm.

Intended Use: Bone Level Tapered Implants	Straumann® Bone Level Tapered Implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann Bone Level Tapered Implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments).
Materials:	Versions of the subject devices will be produced from a titanium-13zirconium alloy, trade named Roxolid®, as previously reviewed and cleared to market per premarket notification submission K140878. The transfer piece is produced from titanium-6aluminum-7niobium alloy (TAN). This is the same material as for the predicate transfer pieces cleared to market per premarket notification submission K140878.
Technological Characteristics:	The subject devices are identical in every respect to the identified Bone Level Tapered predicate devices with the exception of overall length; the subject device is 18 mm in length where the longest previously cleared Bone Level Tapered devices previously cleared to market per K140878 and K150938 is 16 mm in length. The 18 mm length subject devices have the same length as the Neodent CM Drive device cleared to market per K150182, however the Neodent CM Drive devices have a minimum diameter of ∅3.5 mm where the subject device has a minimum diameter of ∅3.3 mm.

Feature	Primary Predicate Device Bone Level Tapered Implants (K140878)	Subject Devices Bone Level Tapered Implants
Indications For Use	Straumann® dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments).	Straumann® Bone Level Tapered Implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann Bone Level Tapered Implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments).
Implant-to-Abutment Connection	Narrow CrossFit® (NC) Regular CrossFit® (RC)	Narrow CrossFit® (NC) Regular CrossFit® (RC)
Implant Diameter	Ø3.3mm, Ø4.1mm, Ø4.8mm	Ø3.3mm, Ø4.1mm, Ø4.8mm
Implant Length	8, 10, 12, 14, 16 mm	18 mm
Coronal Thread Form	Constant major and minor thread diameters (i.e., parallel wall) 0.8mm thread pitch	Constant major and minor thread diameters (i.e., parallel wall) 0.8mm thread pitch
Material	Titanium Grade 4 Titanium zirconium alloy Ti-13Zr	Titanium zirconium alloy Ti-13Zr
Surface Finish	SLA SLActive	SLA SLActive

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. The following studies are incorporated into this submission by reference to the submission for the primary predicate (K140878):

- Dynamic fatigue test data consistent with FDA guidance and ISO 14801
- Biological compatibility per the ISO 10993 series standards
- Sterilization validation per the ISO 11137 series standards
- Shelf life (stability) per ASTM F1980

In order to confirm that the reduced minimum implant diameter between the subject device (∅3.3 mm) and the Neodent CM Drive reference device (∅3.5 mm) does not result in a new failure mode, the following additional bench study was performed on all three diameters of the subject device:

- Peak insertion torque was measured while driving the implants to a clinically appropriate position relative to the surface of simulated bone material (polyurethane foam) having densities of between 10 and 40 pounds per cubic foot that had been prepared per the instructions for use.

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.