Straumann USA, LLC
Jennifer Jackson
Director, Regulatory Affairs & Quality
60 Minuteman Road
Andover, Massachusetts 01810

January 19, 2018

Re: K171784
Trade/Device Name: Straumann® Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: December 19, 2017
Received: December 20, 2017

Dear Jennifer 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)*

K171784

Device Name

Straumann® Dental Implant System

Indications for Use *(Describe)*

Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are also indicated 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 through the corresponding components (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 K171784

5.1 Submitter

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

60 Minuteman Road

Andover, MA 01810

Contact Person: Jennifer M. Jackson, MS

Phone Number: 1-978-747-2509

Fax Number: 1-978-747-0023

Date of Submission: January 19, 2018

5.2 Device

Trade Name: Straumann® Dental Implant System

Common Name: Dental Implants

Classification Name: Implant, Endosseous, Root-form

Regulatory Class: DZE

Product Code: Class II (21 CFR 872.3640)

5.3 Predicate Device

Primary Predicate: Straumann® Dental Implant System (K130222)

Reference Predicate: Straumann® Bone Level Tapered Implants (K140878)

Straumann® Bone Level Tapered Implants (K153758)

5.4 Device Description

The Straumann® Dental Implant System is an integrated system of endosseous dental implants with corresponding abutments, healing abutments, closure screws and surgical and prosthetic parts and instruments.

The Straumann® Dental Implant System includes the following dental implants:

SLActive® and Roxolid®, Standard, Ø3.3 RN, 8, 10, 12, 14, and 16 mm

SLActive® and Roxolid®, Standard, Ø4.1 RN, 6, 8, 10, 12, 14, and 16 mm

SLActive® and Roxolid®, Standard, Ø4.8 RN, 6, 8, 10, 12, and 14 mm

SLActive® and Roxolid®, Standard, Ø4.8 WN, 6, 8, 10, and 12 mm

SLActive® and Roxolid®, Standard Plus, Ø3.3 RN, 8, 10, 12, and 14 mm

SLActive® and Roxolid®, Standard Plus, Ø4.1 RN and Ø4.8 RN, 6, 8, 10, 12, and 14 mm

SLActive® and Roxolid®, Standard Plus, Ø4.8 WN, 6, 8, 10, 12, and 14 mm

SLActive® and Roxolid®, Tapered Effect, Ø3.3 RN and Ø4.1 RN, 8, 10, 12, and 14 mm

SLActive® and Roxolid®, Tapered Effect, Ø4.8 WN, 10, 12, and 14 mm

SLActive® and Roxolid®, Bone Level, Ø3.3 NC, Ø4.1 RC, and Ø4.8 RC, 8, 10, 12, and 14 mm

SLActive® and Roxolid®, Bone Level Tapered, Ø3.3 NC, Ø4.1 RC, and Ø4.8 RC, 8, 10, 12, 14, and 18 mm

5.5 Indications for Use

Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are also indicated 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 through the corresponding components (abutments).

There are no changes to the Indication for Use being introduced as a result of this submission. The Indications for Use statement of the subject device is identical to that of the primary predicate.

5.6 Technological Characteristics

Straumann® Dental implants are solid screw implants manufactured from titanium-zirconium alloy (Roxolid®) or titanium Grade 4. The implant surface is large-grit

sandblasted and acid-etched. In addition, SLActive® is in a chemically activated state, which is preserved by storage in a NaCl solution.

The subject devices are identical to the corresponding Straumann predicate devices with respect to design, materials, surface treatments, fundamental operating principles, and sterilization processes and procedures. The change proposed in this premarket notification modifies the Instructions for Use for the Roxolid® SLActive® and Titanium SLActive® dental implants, removing Type II Diabetes and patients previously irradiated in the head and neck from the Cautions/Precautions in the Instructions for Use.

There are no changes to or new surgical instruments or secondary components being introduced as a result of the proposed change.

5.7 Performance Data

The bench and animal performance testing previously submitted in support of the referenced Straumann predicate devices 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 continue to be representative of the performance of the subject devices.

A review and summarization of published literature regarding dental implant treatment in patients suffering from Diabetes Mellitus (DM) and patients previously irradiated in the head and neck area is being provided in support of the proposed change to the Instructions for Use content (Cautions / Precautions) of the subject device.

In patients with Type II Diabetes Mellitus, most analyzed reviews found no statistically significant difference in the implant failure rate in diabetic and non-diabetic patients. The studies with Straumann implants in general and SLActive implants in particular reported a survival rate between 96.6% and 100% for patients with Type II Diabetes Mellitus (HbA1c levels between 6 and 12%). The most common adverse events were rotational movement of the implant, tenderness or pain at the implant site, pain on rotation of the transgingival healing cap, and peri-implant mucositis.

For patients with previously irradiated bone for oral cancer, studies with Straumann implants in general and SLActive implants in particular reported survival rates of 90% or 100% up to 5 years after implant placement. Radiation doses ranged from 30-40 Gy to

72 Gy. The time between radio- and implant therapy ranged from 6-12 months. Where included in the studies, restoration was uneventful.

The available data indicate that use of Straumann® SLActive® Implants for dental implant therapy is a predictable treatment option for patients with irradiated bone in the head or neck area and patients suffering from Type II Diabetes Mellitus.

5.8 Conclusion

The documentation submitted in this premarket notification supports the proposed modification to the Instructions for Use of the Roxolid® SLActive® and Titanium SLActive® dental implants. The subject devices are substantially equivalent to the predicate devices.