

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

July 24,2015

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

Re: K150938

Trade/Device Name: Straumann® Dental Implant System – Roxolid® SLA Implants Regulation Number: 21 CFR 872.3640 Regulation Name: Endosseous Dental Implant Regulatory Class: Class II Product Code: DZE Dated: June 19, 2015 Received: June 22, 2015

Dear Mr. 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 <u>Federal Register</u>.

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

<u>http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</u> 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,

Susan Runne DDS, MA

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

Indications for Use

510(k) Number *(if known)* K150938

Device Name

Straumann® Dental Implant System – Roxolid® SLA Implants

Indications for Use (Describe)

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).

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. <u>510(k) Summary – K150938</u>

| 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 and Clinical Affairs | |
| Date Prepared: | July 13, 2015 | |
| 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 [®] Dental Implant System – Roxolid [®] SLA Implants | |
| Predicate Device(s) | This is a bundled 510(k) Premarket Notification. Each of the predicates listed below is a primary predicate for a portion of the subject devices of this submission. K983742 – All in One Two Part Implant (Straumann) K012757 – Tapered Implant Modification (Straumann) K033922 – Standard Plus Implant (Straumann) K062129 – Bone Level Implants (Straumann) K111357 – NNC Roxolid Implant System K140878 – Bone Level Tapered Implants | |
| Reference Device(s) | K033984 – SLActive Surface Finish K081419 – Roxolid Tapered Effect Implants (Straumann) K083550 – Roxolid 3.3 Implants (Straumann) K121131 – Roxolid 4.1/4.8 Bone Level Implants (Straumann) K122855 – Roxolid 4.1/4.8 Tissue Level Implants (Straumann) | |
| Device Description: | The subject devices represent a line extension of the previously cleared implants of the Straumann Dental Implant System. The subject devices represent a full line of Straumann implants having the Ti-13Zr alloy (Roxolid [®]) and the SLA grit blast and acid etch surface finish in the same diameters, lengths, emergence profiles and implant-to abutment interfaces as previously cleared implants in the Straumann Dental Implant System. | |

Intended Use: Strauman[®] 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).

Materials:The subject devices will be produced from a titanium-
13zirconium alloy, trade named Roxolid[®], as previously
reviewed and cleared to market per premarket notification
submissions K111357 for the predicate devices, as well as
K081419, K083550, K121131 and K122855 for the reference
devices.

The transfer piece is produced from titanium-6aluminum-7niobium alloy (TAN) conforming to ISO 5832-11. This is the same material and design as for the predicate transfer pieces cleared to market per premarket notification submissions K140878.

Technological
Characteristics:The subject devices have the same Indications For Use and the
same technical characteristics as the identified predicate and
reference devices, with the exception of the material.
Technological characteristics of the subject devices are
compared with those of the predicate devices in the table below.

| Feature | Subject Devices Roxolid SLA Implants | Predicate Devices Titanium SLA Implants |
|---------------------|---|--|
| Implant-to-Abutment | Narrow CrossFit (NC) | Narrow CrossFit (NC) |
| Connections: | Regular CrossFit (RC) | Regular CrossFit (RC) |
| Bone Level | | |
| Implant-to-Abutment | Narrow Neck CrossFit [®] (NNC) | Narrow Neck CrossFit [®] (NNC) |
| Connections: | Regular Neck (RN) | Regular Neck (RN) |
| Tissue Level | Wide Neck (WN) | Wide Neck (WN) |
| Implant Diameter(s) | Ø3.3mm, Ø4.1mm, Ø4.8mm | Ø3.3mm, Ø4.1mm, Ø4.8mm |
| | | |
| Implant Length(s) | 6.0, 8.0, 10.0, 12.0, 14.0, 16.0 mm | 6.0, 8.0, 10.0, 12.0, 14.0, 16.0 mm |
| | (6.0mm legnth excluded for Ø3.3mm) | (6.0mm length excluded for Ø3.3mm) |
| Surface Finish | SLA | SLA |
| | | |
| Material | Commercially pure Grade 4 | Titaniun-13Zirconium alloy |
| | Titanium | (Roxolid [®]) |

| Primary Package | Vial of styrene-butadiene block | Vial of styrene-butadiene block |
|-----------------|---|---|
| | copolymer (Styrolux), vial cap of | copolymer (Styrolux), vial cap of |
| | LDPE and an implant holder of | LDPE and an implant holder of |
| | Grilamid TR70 polyamide. | Grilamid TR70 polyamide. |
| Sterilization | Gamma Irradiation, 25 kGy min. | Gamma Irradiation, 25 kGy min. |
| | Validated per ISO 11137-1 and ISO | Validated per ISO 11137-1 and ISO |
| | 11137-2 to an SAL of 1 x 10 ⁻⁶ | 11137-2 to an SAL of 1 x 10 ⁻⁶ |

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. Transfer Piece
removal force data has been provided. Surface finish
characteristics and surface chemistry analysis data have also
been provided.

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.