DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 14, 2014

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

Re: K140737
Trade/Device Name: Straumann® CARES® Screw-Retained Bridges and Bars
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: II
Product Code: NHA
Dated: July 17, 2014
Received: July 18, 2014

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 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mary S. Runner -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

4. Indications For Use

510(k) Number (if known): K140737

Device Name: Straumann® CARES® Screw-Retained Bridges and Bars

Indications for Use:

Straumann CARES Screw-Retained Bridges and Bars are indicated for use as bars and bridges that attach to implants and/or to screw-retained abutments of the Straumann Dental Implant System (SDIS) to provide support for prosthetic reconstructions such as bridges and over-dentures. The final processed products have the purpose of restoring chewing function.

Straumann CARES Screw-Retained Bridges and Bars are indicated for screw-retained restorations.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(k) Summary

Submission Number: K140737

Submitter:
Straumann USA, LLC
60 Minuteman Road
Andover, MA 01810
Registration No.: 1222315
Owner/Operator No.: 9005052

Contact Person:
Christopher Klaczyk
Director of Regulatory Affairs and Clinical Research
(978) 747-2575

Date Prepared: March 21, 2014

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

Device Class: II (21 CFR 872.3630)

Classification Panel: Dental

Classification Name: Endosseous dental implant abutment (21 CFR 872.3630)

Proprietary Name:
Straumann® CARES® Screw-Retained Bars
Straumann® CARES® Screw-Retained Bridges

Predicate Device(s):
- Straumann® CARES® Screw-Retained Bridges and Bars (K132844)
- Straumann® Magellan Screw-Retained Abutments (K133421)

Device Description: The Straumann CARES Screw-Retained Bars and Straumann CARES Screw-Retained Bridges are used for the restoration of Straumann dental implants with different endosteal diameters, lengths and platforms and Straumann Screw-Retained Abutments. The bars and bridges presented in the premarket notification submission (identified as "SRBB" for Screw Retained Bars and Bridges) are designed to interface with previously cleared screw-retained abutments (K133421). We also present "multi-level" bars and bridges in this submission designed to interface with any combination of screw-retained abutments (as cleared per premarket notification K133421), Bone Level (BL) implants (as cleared per premarket notification K062129) and Tissue Level (TL) implants (as cleared per premarket notifications K101465 and K112280) of

the SDIS. When SRBB devices are attached directly to dental implants of the SDIS; the abutment/secondary part is an integral part of the SRBB device.

SRBB devices facilitate customization to meet the functional and esthetic requirements of the individual patient. They are patient-specific medical devices, i.e. they are designed by the clinician or dental technician and fabricated by Straumann specifically for an individual patient.

SRBB devices are designed via Straumann approved Computer Aided Design (CAD) software such as Straumann® CARES® Visual. After importing a scan of the patient model, the CAD software is used to generate digital restoration models incorporating the subject devices. The digital restoration model is transferred to the milling center where the restoration is produced using Computer Aided Manufacturing (CAM)-techniques.

Intended Use:

Straumann CARES Screw-Retained Bridges and Bars are indicated for use as bars and bridges that attach to implants and to screw-retained abutments of the Straumann Dental Implant System (SDIS) to provide support for prosthetic reconstructions such as bridges and over-dentures. The final processed products have the purpose of restoring chewing function.

Straumann CARES Screw-Retained Bridges and Bars are indicated for screw-retained restorations.

Materials:

Milling blanks for the fabrication of the subject devices are available in two different materials, a cobalt chromium alloy and commercially pure titanium of grade 4. The basal and occlusal screws are fabricated from a titanium-aluminum-niobium alloy, Ti-6Al-7Nb, also referred to as TAN. All of these materials comply with international standards applicable to materials for dental applications.

Technological Characteristics:

Aside from incorporating features to facilitate connection to Straumann Screw Retained Abutments, the materials, design, fundamental operating principles, manufacturing methods and sterilization method are identical to those of the previously cleared SRBB constructs intended for use with Straumann Bone Level and Tissue Level implants.

No new surgical instruments or secondary components are being introduced as a result of this submission.

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, ISO 14801 and a modified ISO 14801 protocol have been referenced in support of this submission.

Conclusions: Based upon our assessment of the performance data, the subject devices have been determined to be safe and effective for their intended uses and are substantially equivalent to the identified predicate devices.