K130808

510(k) Summary

1. Applicant's Name and Address

JUN 2 8 2013

Straumann USA, LLC (on behalf of Institut Straumann AG)
60 Minuteman Rd.
Andover, MA 01810
Telephone Number: 800-448-8168, ext. 2513
Fax Number: 978-747-0023
Contact Person: Elaine Alan
Regulatory Project Manager

2. Date of Submission: March 22, 2013

3. Name of the Device

Trade Name: Straumann Healing Abutments
Straumann Healing Caps
Straumann Closure Screws

Common Name: Healing Abutment
Healing Caps
Closure Screws

Product Code: NHA

Classification Name: Endosseous Dental Implant Abutments

Regulation Number: §872.3630

4. Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)

K111357, Straumann Narrow Neck CrossFit (NNC) 03.3mm Dental Implant System

K072679, P.004 Abutments

K071585, P.004 Healing Abutments and Closure Screws

K070478, P.004 RC Temporary Abutment, P.004 Temporary Healing Abutment (Cap)

K062129, P.004 Implants

K013798, Prosthetic Accessories to the ITI Dental Implant System

K960634, Titanium Healing Caps

K894844, BoneFit Implant System Accessories and Instruments

5. Description of the Device

The Straumann Healing Abutments, Healing Caps, and Closure Screws are intended for use with the Straumann Tissue Level and Bone Level Dental Implant System to protect the inner configuration of the implant and to maintain, stabilize and form the soft tissue during the healing process. The

devices are available in various diameters and heights, and the material is Titanium for all Healing Abutments, Healing Caps and Closure Screws; the customizable Healing Abutments are made of polyetheretherketone (PEEK) with a Titanium Alloy inlay.

6. Intended Use of the Device

Closure screws, healing caps, and healing abutments are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.

Customizable healing abutments made of PEEK are for use for up to six months.

7. Technological Characteristics

The proposed Sterile Healing Abutments, Healing Caps, and Closure Screws intended use, material, fundamental operating principles and overall design are identical to the predicate devices. The modification of the proposed healing components versus the currently cleared devices is from non-sterile to sterile devices. The non-significant design change of the proposed RC Conical Healing Abutments versus the currently cleared devices is to increase the diameter by 0.5mm.

8. Performance Testing

Verification and validation testing were performed to ensure that the Straumann Sterile Healing Abutments, Healing Caps, and Closure Screws function as intended and that the modifications do not impact the performance of the devices. Testing included:

i. Sterilization validation in accordance with ISO 11137-1:2006: *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of sterilization process for medical devices*, and ISO 11137-2:2006: *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*

1) Requirements were met; there were not deviations to the applicable standards.

ii. Shelf Life validation in accordance ASTM F1980, *Standard Guide for Accelerated Aging of Sterile Medical Device Packages*

1) Requirements were met; there were not deviations to the applicable standard.

9. Conclusion

The results from the testing conducted demonstrated that the Straumann Sterile Healing Abutments, Healing Caps, and Closure Screws function as intended and met the predetermined acceptance criteria.

The results of the verification/validation testing and risk analysis indicate that the Straumann Sterile Healing Abutments, Healing Caps, and Closure Screws perform as intended, are substantially equivalent to the named predicate devices and do not raise new issues of safety and effectiveness.

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

June 28, 2013

Ms. Elaine Alan
Regulatory Project Manager
Straumann USA
60 Minuteman Road
ANDOVER MA 01810

Re: K130808
Trade/Device Name: Straumann Healing Abutments, Healing Caps, and Closure Screws
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 30, 2013
Received: May 31, 2013

Dear Ms. Alan:

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,

Kwame O. Ulmer -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130808

Indications for Use Statement

510(k) Number (if known): K130808

Device Name: Straumann Healing Abutments, Healing Caps, and Closure Screws

Indications for Use:

Closure Screws, healing caps, and healing abutments, are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.

Customizable healing abutments made of PEEK are for use for up to six months.

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)

Sheena A. Green -S
2013.06.28 11:36:22 -04'00' for Susan Runner, DDS, MA

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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