K122192

Straumann Temporary Abutments, PMMA
Traditional 510(k)
Section 5: 510(k) Summary

NOV 2 2012

1. Applicant's Name and Address

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: July 23, 2012

3. Name of the Device

Trade Name: Straumann Temporary Abutments VITA CAD-Temp
Common Name: Temporary Abutments
Classification Name: Endosseous Dental Implant Abutment
Regulation Number: §872.3630

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

K072679, Straumann NC Temporary Abutment
K070478, Straumann RC Temporary Abutment
K051717, Straumann RN synOcta Temporary Abutment
K111357, Straumann NNC Post for Temporary Restoration

5. Description of the Device

Straumann Temporary Abutments VITA CAD-Temp are temporary abutments intended for placement on Straumann Bone Level and Straumann Tissue Level implants of corresponding diameter. The temporary abutments are made of polymethyl methacrylate (PMMA), with a Titanium Alloy inlay.

6. Intended Use of the Device

Straumann Temporary Abutments VITA CAD-Temp are indicated for use with Straumann Bone Level and Tissue Level implants for temporary crown and bridge restorations, and to maintain, stabilize and shape the soft tissue during the healing phase for up to six months, and should be placed out of occlusion.

7. Technological Characteristics

The proposed devices are substantially equivalent to the currently marketed devices. They share the same indication for use, prosthetic platforms, implant/abutment connections, fundamental operating principles, and contact duration of up to six months. Changes to the proposed devices are listed below followed by a comparison table, Table 1, listing each proposed and predicate device and the respective changes:

- Material change from PEEK to PMMA, and from Titanium Alloy to PMMA,
- Design changes of the coronal aspects of the abutments including length and diameter.

Table 1: Comparison Table

Change	Proposed Device NC Temporary Abutment, PMMA	Predicate Device NC Temporary Abutment, PEEK
Material	PMMA, polymethyl methacrylate	PEEK, polyetheretherketone
Length	14.65mm	14.75mm
Change	Proposed Device RC Temporary Abutment, PMMA	Predicate Device RC Temporary Abutment, PEEK
Material	PMMA, polymethyl methacrylate	PEEK, polyetheretherketone
Length	16.30mm	16.40mm
Change	Proposed Device RN Temporary Abutment, PMMA	Predicate Device RN synOcta Temporary Abutment, PEEK
Material	PMMA, polymethyl methacrylate	PEEK, polyetheretherketone
Change	Proposed Device WN Temporary Abutment, PMMA	Predicate Device RN synOcta Temporary Abutment, PEEK
Material	PMMA, polymethyl methacrylate	PEEK, polyetheretherketone
Diameter	10.10mm	7.0mm
Implant Compatibility	Ø 4.8mm Wide Neck Tissue Level Implant	Ø3.3, 4.1 and 4.8mm Regular Neck Tissue Level Implants
Prosthetic Platform	Ø 6.5mm	Ø 4.5mm
Change	Proposed Device NNC Temporary Abutment, PMMA	Predicate Device NNC Post for Temporary Restoration,
Material	PMMA, polymethyl methacrylate Titanium Alloy Inlay, Ti6Al7Nb	Titanium Alloy, Ti6Al7Nb
Diameter	5.0mm	3.70 mm

8. Performance Testing

Verification and validation testing were performed to ensure that the devices subject to this 510(k) Premarket Notification function as intended and that design input matches design output. Testing included:

1. Performance Testing
    i. FDA guidance document "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments."
        1. Fatigue testing was performed in accordance to the test set-up of the guidance document for systems that include polymeric components. Compressive and shear (lateral) forces were tested; successful testing was measured by the predetermined acceptance criteria which was based on the predicate devices. Angled abutment testing was not performed as no angled devices were proposed. The proposed devices met or surpassed the acceptance criteria.
2. Sterilization Validation
    i. Sterilization validation was carried out in accordance with ISO 17665-1 (overkill method, partial cycle): Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices, and ISO 17665-2: First edition 2009-01-15 Technical Specification Sterilization of health care products - Moist heat – Part 2: Guidance on the application of ISO 17665-1.
        1. Requirements were met; there were no deviations to the applicable standards.

9. Conclusion

The results from the testing conducted demonstrated that the Straumann Temporary Abutments VITA CAD-Temp function as intended and met the pre-determined acceptance criteria.

The results of the performance bench testing and risk analysis indicate that the Straumann Temporary Abutments VITA CAD-Temp are substantially equivalent to the named predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

NOV 2 2012

Straumann USA, Limited Liability Company
Ms. Elaine Alan
Regulatory Project Manager
60 Minuteman Road
Andover, Massachusetts 01810

Re: K122192
Trade/Device Name: Straumann Temporary Abutments VITA CAD-Temp
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: October 8, 2012
Received: October 9, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance.. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Straumann Temporary Abutments VITA CAD-Temp

Indications for Use:

Straumann Temporary Abutments VITA CAD-Temp are indicated for use with Straumann Bone Level and Tissue Level implants for temporary crown and bridge restorations, and to maintain, stabilize and shape the soft tissue during the healing phase for up to six months, and should be placed out of occlusion.

Prescription Use__X__ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number: K122192