K113410/S1

JAN 13 2012

1. Applicant's Name and Address

Straumann US (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
Senior Regulatory Affairs Specialist

2. Date of Submission: November 17, 2011

3. Name of the Device

Trade Name:	Straumann Narrow Neck CrossFit (NNC) Solid Abutments Straumann Narrow Neck CrossFit (NNC) Temporary Copings Straumann Narrow Neck CrossFit (NNC) Protective Caps
Common Name:	NNC Solid Abutments NNC Temporary Copings NNC Protective Caps
Classification Name:	Endosseous Dental Implant Abutments
Regulation Number:	§872.3630

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

Straumann Regular Neck (RN) Solid Abutment, K894844

Straumann Narrow Connection (NC) Temporary Copings, and Straumann Narrow Connection (NC) Protective Caps, K080286

5. Description of the Device

Straumann Narrow Neck CrossFit (NNC) Solid Abutments are permanent abutments intended for placement onto the Straumann Narrow Neck CrossFit (NNC) tissue level Implants with the diameter of 3.3mm, K111357. The abutments are made of Titanium Grade 4. The abutments are available in straight configurations only. Temporary abutments, copings and protective caps are indicated for temporary usage of up to 180 days (Ti, TAN, PEEK). Temporary copings made from PMMA are intended for temporary usage up to 30 days

6. Indications for Use

Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. The specific indications for use for each device table are specified in the table below.

	Indications for Use		
Device type (as indicated on product label)	crown	bridge	Overdentures
Anatomic Abutment Cementable Abutment Solid abutment synOcta® Milling Cylinder synOcta abutment Meso Abutment	X	X	
Multi-Base Abutment Coping, Ti		X	X
synOcta® 1.5 abutment	X	X	X
Temporary Abutment Post for temporary restoration Temporary Coping	X	X	

Temporary abutments, copings and protective caps are indicated for temporary usage of up to 180 days (Ti, TAN, PEEK). Temporary copings made from PMMA are intended for temporary usage up to 30 days.

7. Technological Characteristics

The proposed devices are substantially equivalent to the currently marketed devices. They share the same indications for use, fundamental operating principles, and materials.

8. Performance Testing

Verification and validation testing were performed to ensure that the Straumann Narrow Neck CrossFit (NNC) Solid Abutments function as intended

and that the modifications do not impact the performance of the device. Testing included:

1. Performance Testing
    i. Fatigue Testing in accordance to FDA guidance document "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments."

Verification and validation testing were performed to ensure that the Straumann Narrow Neck CrossFit (NNC) Temporary Copings and the Straumann Narrow Neck Crossfit (NNC) Protective Caps function as intended and that the modifications do not impact the performance of the device. Temporary copings are placed out of occlusion. Protective caps do not support a restoration. Testing included:

1. Functional Inspection Test
2. Dimensional Inspections

9. Conclusion

The results from the testing conducted demonstrated that the Straumann Narrow Neck CrossFit (NNC) Solid Abutments, Temporary Copings, and Protective Caps function as intended and met the pre-determined acceptance criteria.

The Straumann Narrow Neck CrossFit (NNC) Solid Abutments, Temporary Copings, and Protective Caps is a validated system. The results of the performance bench testing and risk analysis indicate that the Straumann Narrow Neck CrossFit (NNC) Solid Abutments, Temporary Copings, and Protective Caps are substantially equivalent to the named predicate devices and are safe and effective for their intended use.

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

JAN 13 2012

Ms. Elain Alan
Straumann USA
Senior Regulatory Affairs Specialist
60 Minuteman Road
Andover, Massachusetts 01810

Re: K113410
Trade/Device Name: Straumann Narrow Neck CrossFit (NNC) Solid Abutments
Straumann Narrow Neck CrossFit (NNC) Temporary Copings
Straumann Narrow Neck CrossFit (NNC) Protective Caps
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 22, 2011
Received: December 23, 2011

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

K113410/S1

Indications for Use Statement

510(k) Number (if known):

Device Name: Straumann Narrow Neck CrossFit (NNC) Solid Abutments

Indications for Use:
Abutments are used in connection with the prosthetic restoration of Straumann dental implants. Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges.

Narrow Neck CrossFit Solid Abutments are indicated for cement-retained single tooth and bridge restorations.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K113410

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Indications for Use Statement

510(k) Number (if known):

Device Name: Straumann Narrow Neck CrossFit (NNC) Temporary Copings

Indications for Use:
Temporary Copings made from PEEK (polyether etherketone) are intended to serve as a base for temporary restorations for up to 180 days.

Temporary Copings made from PMMA (polymethyl methacrylate) are intended to serve as a base for temporary restorations for up to 30 days

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

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Indications for Use Statement

510(k) Number (if known):

Device Name: Straumann Narrow Neck CrossFit (NNC) Protective Caps

Indications for Use:
Protective Caps are intended to protect the outer configuration of the abutment and to maintain and condition the contours of the soft tissue during the healing phase for up to 6 months.

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

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