Narrow Neck CrossFit (NNC) Cementable Abutments
Special 510(k)
Section 5: 510(k) Summary

DEC 2 8 2011

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 4, 2011

3. Name of the Device

Trade Name:	Straumann Narrow Neck CrossFit (NNC) Cementable Abutments
Common Name:	NNC Cementable Abutments
Classification Name:	Endosseous Dental Implant Abutments
Regulation Number:	§872.3630

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

Straumann Narrow Neck Connection (NNC) Gold Abutment for crowns, K111357
Straumann Narrow Connection (NC) Cementable Abutments, K080286
Straumann Narrow Neck (NN) CARES Titanium Abutment, K082545

5. Description of the Device

Straumann Narrow Neck CrossFit (NNC) Cementable Abutments are permanent abutments intended for placement onto the Straumann Narrow Neck CrossFit (NNC) tissue level Implants with the diameter of 3.3mm. The abutments are made of Titanium Grade 4 with a corresponding basal screw made of Titanium Alloy. The abutments are available in straight and 15° angled configurations.

6. Intended Use of the Device

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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. Straumann Narrow Neck CrossFit (NNC) Cementable Abutments are indicated for cement-retained single tooth and bridge restorations.

7. Technological Characteristics

The proposed device is substantially equivalent to the currently marketed device. They share the same indication for use, prosthetic platform, implant/abutment connection, and fundamental operating principles.

8. Performance Testing

Verification and validation testing were performed to ensure that the Straumann Narrow Neck CrossFit (NNC) Cementable 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."

9. Conclusion

The results from the testing conducted demonstrated that the Sraumann Narrow Neck CrossFit (NNC) Cementable Abutments function as intended and met the pre-determined acceptance criteria.

K113283

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The Straumann Narrow Neck CrossFit (NNC) Cementable Abutments is a validated system. The results of the performance bench testing and risk analysis indicate that the Straumann Narrow Neck CrossFit (NNC) Cementable Abutments are substantially equivalent to the named predicate device and is safe and effective for its 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

DEC 2 8 2011

Ms. Elaine Alan
Senior Regulatory Affairs Specialist
Straumann USA
60 Minuteteman Road
Andover, Massachusetts 01810

Re: K113283
Trade/Device Name: Straumann Narrow Neck CrossFit (NNC) Cementable Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 9, 2011
Received: December 12, 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

K113283

Indications for Use

510(k) Number (if known):

Device Name: Straumann Narrow Neck CrossFit (NNC) Cementable 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 Cementable Abutments are indicated for cement-retained single tooth and bridge 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 DCRH, Office of Device Evaluation (ODE)

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

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