K112280

NOV 16 2011

straumann

510(k) Summary

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: August 8, 2011

3. Name of the Device

Trade Name: Straumann® CARES® Screw-retained Bridge Ti
Straumann® CARES® Dolder® Bar Ti
Common Name: Implant Bridge
Classification Name: Endosseous Dental Implant Abutment
Regulation Number: §872.3630

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

- K101465, Straumann® CARES® Screw-retained Bridge and Straumann® CARES® Dolder® Bar

5. Description of the Device

Straumann CARES Screw-retained Bridge, Titanium (Ti) and Straumann CARES Dolder Bar Titanium (Ti) are dental restorative devices intended to be attached directly to dental implants by basal screws. Straumann CARES Screw-retained Bridge Ti and Straumann CARES Dolder Bar Ti are designed with implant interfaces comparable to a single tooth abutment which are attached to a Straumann implant with prosthetic platforms Regular Neck (RN) Ø4.8mm and Wide Neck (WN) Ø6.5mm.

The implant positions and oral situation are recognized by a scan of a dental master model with implant analogs and scanbodies. Based on the scan data, the dental technician selects the proper implant interfaces and designs the bar or bridge according to a dentist's prescription. Once the Straumann CARES Screw-retained Bridge Ti and Straumann CARES Dolder Bar Ti is designed the digital dataset is sent to Straumann CADCAM by internet connection where the bridge or bar is milled from a Titanium-based blank.

Straumann CARES Screw-retained Bridge Ti and Straumann CARES Dolder Bar Ti allow for individual customization regarding function and esthetics. They attach directly to Straumann dental implants. The device is intended to be finished into a bridge or overdenture using standard dental laboratory techniques and materials. The devices are CAD-derived, CAM-produced and have a scanner as its data source.

The milling blanks used for the manufacture of Straumann CARES Screw-retained Bridge Ti and Straumann CARES Dolder Bar Ti are manufactured from Titanium, grade 4, which is biocompatible for its intended use.

6. Intended Use

Straumann CARES Screw-retained Bridge Ti and Straumann CARES Dolder Bar Ti are indicated for use as bars and bridges that attach to dental implants (Straumann implant Regular Neck (RN) Ø4.8mm and Wide Neck (WN) Ø6.5mm) in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

The Straumann CARES Screw-retained Bridge Ti can be designed for specific patient sizes and spans that are attached to 2 to16 implants.

The Straumann CARES Dolder Bar Ti can be designed for specific patient sizes and spans that are attached to 2 to 10 implants.

7. Technological Characteristics

The Straumann CARES Screw-retained Bridge Ti and Straumann CARES Dolder Bar Ti are equivalent to the predicate device in design, fundamental operating principles, and intended use. Table 1 compares the Straumann CARES Screw-retained Bridge and Straumann CARES Dolder Bar to the predicate device. The proposed devices are milled from blank discs of Titanium, grade 4, which is widely used in the medical industry and is well known to be biocompatible. The Straumann CARES Screw-retained Bridge Ti and Straumann CARES Dolder Bar Ti are designed using Straumann's CAD designing software, Straumann CARES® Visual®, and CAM milled at Straumann's central milling centers. This is the identical CADCAM designing and milling process as the predicate device.

Table 1: Comparison Matrix

Feature	Proposed Device Straumann CARES Screw-retained Bridge Ti and Straumann CARES Dolder Bar Ti	Predicate Device Straumann CARES Screw-retained Bridge and Straumann CARES Dolder Bar
510(k) Number	Subject Submission	K101465
Intended Use	Same	The Straumann® CARES® Screw-retained Bridge and Straumann® CARES® Dolder® Bar are indicated for use as bars and bridges that attach to dental implants (Straumann Regular Neck (RN) Ø4.8mm and Wide Neck (WN) Ø6.5mm) in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function. The Straumann CARES® Screw-retained Bridge is available in different sizes and spans and can be fitted on 2 to 16 implants. The Straumann CARES Dolder Bar

Feature	Proposed Device Straumann CARES Screw-retained Bridge Ti and Straumann CARES Dolder Bar Ti	Predicate Device Straumann CARES Screw-retained Bridge and Straumann CARES Dolder Bar
		is available in different sizes and spans and can be fitted on 2 to 10 implants.
Material	Titanium, grade 4	Coron, Cobalt-Chromium alloy
Implant Compatibility	same	Straumann Regular Neck (RN) Ø4.8mm and Wide Neck (WN) Ø6.5mm
Design Software	Same	Straumann CARES Visual
Basal Screw	Same	Titanium Alloy, Ti6Al7Nb

The proposed devices are substantially equivalent to the currently marketed predicate devices.

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. Fatigue Testing was performed utilizing pertinent testing procedures defined in the FDA guidance document "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments," and ISO 14801:2007, "*Dentistry-Implants-Dynamic fatigue test for endosseous dental implants*." Table 2 lists tests performed and results.

Table 2

Test Performed	Acceptance Criteria	Result
Minimal body testing	Meet or Exceed Predicate Device	Passed
Free hanging bridge	Meet or Exceed Predicate Device	Passed
Free end pontic bridge	Meet or Exceed Predicate Device	Passed

ii. Metal-Ceramic bond testing in accordance with ISO 9693: Metal-ceramic dental restorative systems: requirements satisfied.

9. Conclusion

The results from the testing conducted demonstrated that the Straumann CARES Screw-retained Bridge Ti and Straumann CARES Dolder Bar Ti functions as intended and met the pre-determined acceptance criteria.

The Straumann CARES Screw-retained Bridge Ti and Straumann CARES Dolder Bar Ti is a validated device. The results of the performance bench testing and risk analysis indicate that the Straumann CARES Screw-retained Bridge Ti and Straumann CARES Dolder Bar Ti is substantially equivalent to the identified 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

NOV 16 2011

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

Re: K112280
Trade/Device Name: Straumann® CARES® Screw-retained Bridge Titanium
Straumann® CARES® Dolder® Bar Titanium
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: October 14, 2011
Received: October 17, 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

K112280

Indications for Use

510(k) Number (if known):

Device Name: Straumann® CARES® Screw-retained Bridge Titanium
Straumann® CARES® Dolder® Bar Titanium

Indications for Use:

The Straumann® CARES® Screw-retained Bridge Titanium and Straumann® CARES® Dolder® Bar Titanium are indicated for use as bars and bridges that attach to dental implants (Straumann Regular Neck (RN) Ø4.8mm and Wide Neck (WN) Ø6.5mm) in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

The Straumann® CARES® Screw-retained Bridge Titanium is available in different sizes and spans and can be fitted on 2 to 16 implants.

The Straumann® CARES® Dolder® Bar Titanium is available in different sizes and spans and can be fitted on 2 to 10 implants.

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 DCRH, Office of Device Evaluation (ODE)

Susan Runner

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

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