



Food and Drug Administration
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August 10, 2015

Straumann USA, LLC
Christopher Klaczyk
Director of Regulatory Affairs and Clinical Research
60 Minuteman Road
Andover, Massachusetts 01810

Re: K150814
Trade/Device Name: Straumann Screw-Retained Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 6, 2015
Received: July 8, 2015

Dear Mr. Klaczyk:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Erin I. Keith -S

Erin I. Keith, M.S.

Director

Division of Anesthesiology,

General Hospital, Respiratory, Infection
Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K150814

Device Name
Straumann Screw Retained Abutments

Indications for Use (Describe)

The Straumann® screw-retained abutments are indicated to be placed into Straumann® dental implants to provide support for prosthetic reconstructions such as crowns, bridges and bars.

The final processed devices have the purpose of restoring chewing function.

Straumann® screw-retained abutments are indicated for screw-retained restorations.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K150814

Submitter: Straumann USA, LLC
(on behalf of Institut Straumann AG)
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Andover, MA 01810

Contact Person: Christopher Klaczyk
Director of Regulatory and Clinical Affairs
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Preparation Date: August 5, 2015

Product Code: NHA (21 CFR §872.3630)

Device Class: II (21 CFR §872.3630)

Classification Panel: Dental

Classification Name: Endosseous dental implant abutment (21 CFR §872.3630)

Proprietary Name: Straumann® Screw-Retained Abutment

Primary Predicate: (K133421) Straumann® Magellan™ Screw Retained Abutment System

Reference Devices: None

Device Description: The subject device is a modification of the NC Straight Ø4.6 mm GH 1.0 mm Screw Retained Abutment originally cleared to market per K133421. Dimensional changes have resulted in improved dynamic fatigue performance such that this device can now be used in the pre-molar region of the mouth in addition to the incisors.

Indications For Use: The Straumann® Screw-Retained Abutments are indicated to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns, bridges and bars.

The final processed devices have the purpose of restoring chewing function.

Straumann® Screw-Retained Abutments are indicated for screw-retained restorations.

Intended Use: Straumann® Screw-Retained Abutments are intended to be placed into Straumann® dental implants to provide support for prosthetic reconstructions such as crowns and bridges.

Technological Characteristics: See table below.

Feature	Subject Device Straumann® Screw-Retained Abutment	Primary Predicate Device Straumann® Magellan™ Screw- Retained Abutments (K133421)	Equivalence Discussion
Indications For Use	Straumann® Screw-Retained Abutments are indicated to be placed into dental implants to provide support for prosthetic reconstructions such as crown, bridges and bars. The final processed devices have the purpose of restoring chewing function. Straumann® screw-retained abutments are indicated for screw-retained restorations.	Straumann® Magellan™ Screw-Retained Abutments are indicated to be placed into dental implants to provide support for prosthetic reconstructions such as crown, bridges and bars. The final processed devices have the purpose of restoring chewing function. Magellan™ abutments are indicated for screw-retained restorations.	Equivalent Magellan project name is not being used as a trade name.
Abutment Material	Titanium Alloy (Ti-6Al-7Nb)	Titanium Alloy (Ti-6Al-7Nb)	Identical
Abutment Platform Diameter	Ø 4.6 mm	Ø 4.6 mm	Identical
Abutment Platform Thickness	0.55 mm	0.20 mm	Equivalent The platform thickness does not affect the implant or the prosthetic interfaces of the abutment; affecting only the emergence profile between the implant and the abutment platform.
Gingival Height	1 mm	1 mm	Identical
Abutment Apical Geometry	Engaging Bone Level NC	Engaging Bone Level NC	Identical

Feature	Subject Device Straumann® Screw-Retained Abutment	Primary Predicate Device Straumann® Magellan™ Screw- Retained Abutments (K133421)	Equivalence Discussion
Abutment Coronal Geometry	Straight, 22° Conic taper, 1.9 mm tall, with milled flats; supports engaging and non-engaging protheses	Straight, 22° Conic taper, 1.9 mm tall, with milled flats; supports engaging and non-engaging protheses	Identical
Packaging	PETG thermoformed tray with Tyvek 1073B lid	PETG thermoformed tray with Tyvek 1073B lid	Identical
Sterilization	Device provided non-sterile. Instructions provided for terminal sterilization by the clinician via steam at 134°C for 5 minutes.	Device provided non-sterile. Instructions provided for terminal sterilization by the clinician via steam at 134°C for 5 minutes.	Identical

**Substantial
Equivalence
Discussion:**

The Indications For Use of the subject and predicate devices are the same. The overall abutment material, height, diameter, implant-to-abutment interface, coronal geometry, packaging and sterilization method are unchanged.

The only difference between the subject Straumann® NC Straight Ø4.6 mm GH 1.0 mm Screw-Retained Abutment and the predicate Straumann® NC Straight Ø4.6 mm GH 1.0 mm Screw-Retained Abutment cleared to market per K133421 is the angle of the transition between the apical implant-to-abutment interface and the coronal restoration platform resulting from a change in the thickness of the restoration platform. This change in the external geometry has resulted in greater wall thickness in the flexure zone of the abutment which has resulted in improved dynamic fatigue performance.

**Performance
Testing:**

Bench testing was performed to evaluate the fatigue load limits of the proposed Straumann® Screw-Retained Abutment. Dynamic fatigue tests were conducted in accordance with the FDA guidance document dated May 12, 2004: *“Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments”* and ISO 14801.

Conclusion:

Based upon our assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate devices.