DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 7, 2014

Straumann USA, Limited Liability Company
Mr. Christopher Klaczyk
Director of Regulatory Affairs & Clinical Research
60 Minuteman Road
Andover, MA 01810

Re: K141871
Trade/Device Name: Straumann® Screw Retained Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 9, 2014
Received: July 11, 2014

Dear Mr. Klaczyk:

This letter corrects our substantially equivalent letter of August 7, 2014.

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" (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 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,

Mary S. Runner -S

Erin I. Keith
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 4. Indications For Use

510(k) Number (if known): K141871

Device Name: Straumann® Screw Retained Abutments

Indications for Use:

The Straumann® Screw Retained Abutments are indicated to be placed into the implants of the Straumann® Dental Implant System 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.

| | | |
|---|---|---|
| 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 CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
2014.08.07 13:44:29 -04'00'

## 5. 510(k) Summary

**Submitter:** Straumann USA, LLC (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810
Registration No.: 1222315 Owner/Operator No.: 9005052

**Contact Person:** Christopher Klaczyk
Director of Regulatory Affairs and Clinical Research
Tel.: (978) 747-2575

**Date Prepared:** July 9, 2014

**Product Code(s):** NHA (21 CFR 872.3630)

**Device Class:** II (21 CFR 872.3630)

**Classification Panel:** Dental

**Classification Name:** Endosseous dental implant abutments (21 CFR 872.3630)

**Proprietary Name:** Straumann® Screw Retained Abutments

**Predicate Device(s):**

- Straumann® Magellan Abutment System (K133421)

**Device Description:** The proposed Straumann® NC Angled Screw Retained Abutments are a line extension of the NC Straight and RC Straight and Angled Screw Retained Abutments cleared to market per premarket notification submission K133421.

The Straumann® NC Angled Screw Retained Abutments include 17º and 30º abutments. This is consistent with the RC Angled Screw Retained Abutments cleared to market per premarket notification submission K133421.

**Intended Use:** The Straumann® Screw Retained Abutments are indicated to be placed into the implants of the Straumann® Dental Implant System 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.

**Materials:** The subject devices are produced from titanium-6aluminum-7niobium alloy (TAN) conforming to ISO 5832-11. This is the same material as for the predicate abutments cleared to market per premarket notification submission K133421.

**Technological Characteristics:** The proposed Straumann® NC Angled Screw Retained Abutments are manufactured using precision machining systems from solid material (i.e. one-piece construction). All technological characteristics of the subject devices are the same as for devices as shown in the table below.

| Feature | Subject Devices<br>NC Angled Screw Retained Abutments | Predicate Devices<br>Magellan Abutment System<br>K133421 |
|---|---|---|
| **Implant-to-Abutment Connection** | Narrow CrossFit (NC) | Narrow CrossFit (NC)<br>Regular CrossFit (RC) |
| **Interface Type** | Engaging | Engaging |
| **Platform Diameter(s)** | NC: Ø4.6 mm | NC: Ø3.5 mm, Ø4.6 mm<br>RC: Ø4.6 mm |
| **Abutment Angulation(s)** | NC: 17°, 30° | NC: 0°<br>RC: 0°, 17°, 30° |
| **Gingival Height(s)** | NC Angled: 2.5 mm, 4.0 mm | NC Straight: 1.0, 2.5 and 4.0 mm<br>RC Straight: 1.0, 2.5 and 4.0 mm<br>RC Angled: 2.5 and 4.0 mm |
| **Orientation of Angulation to Engagement Features** | NC: Type A (45°), Type B (0°) | NC: N/A<br>RC: Type A (45°), Type B (0°) |
| **Material** | Ti-6Al-7Nb titanium alloy | Ti-6Al-7Nb titanium alloy |
| **Primary Package** | Medical grade polyethylene blister with a sealing lid | Medical grade polyethylene blister with a sealing lid |
| **Sterilization** | Non-sterile; intended for terminal sterilization via moist heat (autoclave) | Non-sterile; intended for terminal sterilization via moist heat (autoclave) |

**Performance Data:** Per *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments* dated May 12, 2004, the substantial equivalence of the subject device(s) are satisfactorily addressed via bench studies. Dynamic fatigue test data consistent with FDA guidance and ISO 14801 have been referenced in support of this submission.

**Conclusions:** 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.