APR 17 2014

5. 510(k) Summary – K133421

SUBMITTER:	Straumann USA, LLC (on behalf of Institut Straumann AG) 60 Minuteman Road Andover, MA 01810
CONTACT PERSON:	Charlotte Ringleb Regulatory Affairs Associate charlotte.ringleb@straumann.com 978-.747.2552
SUBMISSION DATE	November 5, 2013
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 Magellan Screw-Retained Abutment System
PREDICATE DEVICES	(K990342) Straumann® synOcta screw-retained 1.5 mm Abutment Line (K080239) Straumann® RC/NC Bar and Bridge Abutment Line (K072071) Straumann® Bone Level Cementable Screw (K101945) Neodent CM Exact Mini Angled Abutment
DEVICE DESCRIPTION	This proposed Magellan™ Bone Level Abutment System is based upon the currently cleared Regular CrossFit® (RC) and Narrow CrossFit® (NC) screw-retained Bar and Bridge Abutment Line under premarket notification K080239. The Magellan product line includes one-piece straight abutments for the NC interface, straight and angled (17° and 30°) abutments for the RC interface, basal screws, occlusal screws, protective caps and titanium and gold restorative copings.

INDICATIONS FOR USE

The Straumann Magellan 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.

Magellan abutments are indicated for screw-retained restorations.

TECHNOLOGICAL CHARACTERISTICS

The Straumann Magellan Screw-Retained Abutments, and associated subject devices are manufactured using precision machining systems from solid material (i.e. one-piece construction). Device features faciliate a precise fit with mating features of the previously cleared Straumann Bone Level implants.

FEATURE	SUBJECT DEVICE Magellan Screw-Retained Abutments	PREDICATE DEVICE Bar & Bridge Abutment (K080239)	EQUIVALENCE DISCUSSION
Implant/Abutment Connection	CrossFit® connection with anti-rotation feature	CrossFit® connection without anti-rotation feature	Equivalent Anti-rotation feature not reqired for bar and bridge constructs
Diameter	The diameters are as noted for Regular CrossFit (RC) and Narrow Crossfit (NC): RC: Ø4.6 mm NC: Ø3.5, 4.6 mm	The diameters are as noted for Regular CrossFit (RC) and Narrow Crossfit (NC): RC: Ø4.0, 4.5, 6.5 mm NC: Ø3.5, 4.5 mm	Equivalent The diameters of the subject devices are within the range of the predicate devices.
Gingival Height (GH)	The gingival heights offered follow: 1.0mm 2.5 mm 4.0 mm	The gingival heights offered follow: 1.0 mm 2.5 mm 4.0 mm	Equivalent The gingival heights of the subject devices are within the range of the predicate devices.
Abutment Height	The height of the abutments are as noted: 1.7 mm 1.9 mm	The height of the abutments are as noted: 1.0 mm 4.6 mm	Equivalent The abutment heights of the subject devices are within the range of the predicate devices.

MATERIALS

The Straumann Magellan Screw-Retained Abutments, basal screws and occlusal screws are manufactured from a titanium-aluminium-niobium alloy (Ti-6Al-7Nb or TAN) meeting the requirements of ISO 5832-11. The material for the gold copings is Ceramicor® alloy. The protective caps are produced from polyether ether ketone (PEEK).

PERFORMANCE TESTING

Performance testing of the subject devices was conducted per the FDA guidance *Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseious Dental Implants and Endosseous Dental Abutments* dated May 12, 2004. Bench testing per ISO 14801 was performed to evaluate the dynamic fatigue performance of the subject devices. No animal or human clinical data was provided in support of this submission.

CONCLUSION

The documentation submitted in this premarket notification demonstrates the subject devices and are substantially equivalent to the identified predicate devices.

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

April 17, 2014

Straumann USA, LLC
Ms. Charlotte Ringleb
Regulatory Affairs Specialist
60 Minuteman Road
Andover, MA 01810

Re: K133421
Trade/Device Name: Straumann® Magellan™ Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: March 14, 2014
Received: March 18, 2014

Dear Ms. Ringleb:

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 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. 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,

Erin I. Keith -S

Erin I. Keith, M.S.
Acting 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): K133421

Device Name: Straumann® Magellan™ Abutment System

Indications for Use:

The Straumann® Magellan™ 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.

Magellan™ abutments are indicated for screw-retained restorations.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 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
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