DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 4, 2016

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

Re: K151590
Trade/Device Name: Straumann® synOcta Gold Abutments for Bridge
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 2, 2016
Received: February 3, 2016

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,

Tina Kiang -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*
K151590

Device Name

Straumann® synOcta Gold Abutments for Bridge

Indications for Use *(Describe)*

Prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations.

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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5. 510(k) Summary K151590

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
(978) 747-2575

Date Prepared:
February 23, 2016

Product Code(s):
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)

Common Name:
Endosseous dental implant abutment

Proprietary Name:
Straumann® synOcta Gold Abutments for Bridge

Primary Predicate Device:
K041295, RN synOcta UCLA Gold Abutment (Straumann)

Reference Device(s)
K063789, WN synOcta UCLA Gold Abutment (Straumann)
K133421, Magellan Screw Retained Abutments (Straumann)
K141871, Straumann Screw-Retained Abutments (Straumann)
K150814, Straumann Screw-Retained Abutments (Straumann)

Device Description:
The subject devices represent a line extension of the Straumann Dental Implant System (SDIS). The subject devices are an assembly of a noble metal alloy (Ceramicor®) Abutment Base and a polymer (POM) Modeling Aid. The Modeling Aid is attached to the abutment base by means of a friction fit. The subject devices employ the same Modeling Aid (catalog no. 049.217) as the identified predicate devices. The subject devices use the same Basal Screw for fixing the finished restoration to the implant (catalog no. 049.128) as the identified predicate devices.

The subject devices interface with Straumann Tissue Level (TL) implants having the Regular Neck (RN) or Wide Neck

(WN) implant-to-abutment interface. The subject devices do not engage the anti-rotation features within the TL implants. The non-engaging design makes these devices suitable for the fabrication of bar and bridge superstructures by the dental laboratory using either casting or soldering techniques.

Indications For Use: Prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations.

Materials: The subject devices are an assembly of a noble metal alloy (Ceramicor®) Abutment Base and a polymer (POM) Modeling Aid. The Modeling Aid is sacrificed during the casting procedure and is no longer present in the final restoration.

The Abutment Base of the subject devices consists of the Ceramicor precious metal alloy provided by Cendres + Metaux (Biel-Bienne, Switzerland). Ceramicor is a non-oxidizing alloy for casting-on with precious metal alloys or for soldering with precious metal or non-precious metal alloys. The Melting Range is 1400 – 1490°C (2552 – 2714°F). The 0.2% Proof Strength is 780 N/mm^2 as delivered and 635 N/mm^2 after processing, which satisfies the requirements of a Type 5 material per ISO 22674, *Dentistry -- Metallic materials for fixed and removable restorations and appliances*. The material is self-hardening.

Technological Characteristics: The Abutment Base component of the proposed Straumann® synOcta Gold Abutments for Bridge are manufactured using precision machining systems from solid material (i.e. one-piece construction). The Modeling Aid and Basal Screw components are the same components used for the identified predicate devices. A comparison of the technological characteristics of the subject devices and the predicate devices is provided in the table below.

The Indications for Use language for the subject and primary predicate devices have slightly different. However, this difference in language does not materially change the intended uses of these devices or the determination of substantial equivalence.

Feature	Subject Devices Straumann® synOcta Gold Abutments for Bridge	Primary Predicate Devices Straumann RN synOcta UCLA Gold Abutment (K041295)
Indications For Use	Prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations.	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges.
Implant-to-Abutment Connection	Tissue Level Regular Neck (RN) Tissue Level Wide Neck (WN)	Tissue Level Regular Neck (RN) Tissue Level Wide Neck (WN)
Implant-to-Abutment Platform(s)	Regular Neck (RN) Wide Neck (WN)	Regular Neck (RN) Wide Neck (WN)
Abutment Angulation(s)	Straight, Angled to 30°	Straight
Engagement	Non-engaging; suitable for multi-unit (bridge) restorations	Engaging; suitable for single-unit (crown) restorations
Material(s)	Ceramicor noble metal alloy POM polymer Ti-6Al-7Nb alloy	Ceramicor noble metal alloy POM polymer Ti-6Al-7Nb 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.

Dynamic fatigue test data consistent with FDA guidance and ISO 14801 have been referenced in support of this submission.

New biocompatibility and sterilization studies were not required for the subject devices. The materials of construction and methods of manufacture are the same for the subject device as for the identified Straumann primary predicate device.

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 primary predicate device.