June 28, 2019

Institut Straumann AG
% Jennifer Jackson
Director, Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K190654
Trade/Device Name: Straumann® CI RD Ceramic Healing Caps
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 31, 2019
Received: June 3, 2019

Dear Jennifer Jackson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190654

Device Name

Straumann® CI RD Ceramic Healing Caps

Indications for Use *(Describe)*

Healing Caps are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Healing Caps should be used only with suitable implant connections. The healing components are intended to be used up to 6 months.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1.1 Submitter

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

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Prepared By: Pierre-Yves Calinon – Regulatory Affairs & Compliance Manager

Date of Submission: June 28, 2019

1.2 Device

Trade Name: Straumann® CI RD Ceramic Healing Caps

Common Name: Endosseous Dental Implant Abutment

Classification Name: Endosseous Dental Implant Abutment (21 CFR 872.3630)

Regulatory Class: II

Product Code: NHA

Review Panel: Dental

1.3 Predicate Device

Primary Predicate: K180477 – Straumann PURE Ceramic Implant System

Reference Device: K130808 – Straumann Healing Abutments, Healing Caps, Closure Screws

1.4 Device Description

The Healing Caps are screws machined into 2 pieces and come in three gingival heights to accommodate individual gingival thickness. The material of the devices is yttria-

stabilized tetragonal zirconia (Y-TZP) and titanium grade 4. Healing caps are screwed into the implant to protect the inner configuration in cases of transmucosal healing protocols and are placed out of occlusion and do not support a prosthetic restoration.

1.5 Indications for Use

Healing Caps are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Healing Caps should be used only with suitable implant connections. The healing components are intended to be used up to 6 months.

1.6 Technological Characteristics

The proposed Straumann® CI RD Ceramic Healing Caps intended use and fundamental operating principals are identical to the primary predicated device, K180477. The additional components mentioned in the primary predicate device indications for use statement are not subject to this submission as the change only impacts the Healing Caps. The technological characteristics of the subject devices are compared to the primary predicate and reference devices in Table 1 below.

K190654 – Traditional 510(k) Submission

Straumann® CI RD Ceramic Healing Caps

510(k) Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE
K Number and name of the device	**K190654 Straumann® CI RD Ceramic Healing caps**	**K180477 Straumann PURE Ceramic Implants**	**K130808 Straumann Sterile Healing Solution**
Indications for Use	Healing Caps are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Healing Caps should be used only with suitable implant connections. The healing components are intended to be used up to 6 months.	**Straumann PURE Ceramic Implant:** The Straumann PURE Ceramic Implant is indicated for the restoration of single-tooth gaps and in edentulous or partially edentulous jaws. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components. **Closure and healing caps:** Closure and Healing caps are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Closure and Healing caps should be used only with suitable implant connections. Do not use healing components for longer than 6 months. **Temporary Abutments:** The provisional components are intended to serve as a base for temporary crown or bridge restoration out of occlusion for the Straumann® PURE Ceramic Implant System. The Straumann® Temporary Abutment VITA CAD-Temp® for the Straumann® PURE Ceramic Implant is indicated for temporary usage of up to 180 days. **CI RD Straumann PUREbase Abutments:** CI RD Straumann PUREbase abutment is a titanium base placed onto Straumann ceramic dental implants to provide support for customized prosthetic restorations and is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.	Closure Screws, healing caps, and healing abutments, are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Customizable healing abutments made of PEEK are for use up to six months.
Healing cap material	Y-TZP	**Straumann PURE Ceramic Implant** Y-TZP **Closure and Healing Caps** Titanium Grade 4	Titanium Grade 4
Screw material	Titanium Grade 4 (Ti)	Titanium Grade 4 (Ti)	Titanium Grade 4 (Ti)

K190654 – Traditional 510(k) Submission

Straumann® CI RD Ceramic Healing Caps

510(k) Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE
K Number and name of the device	**K190654 Straumann® CI RD Ceramic Healing caps**	**K180477 Straumann PURE Ceramic Implants**	**K130808 Straumann Sterile Healing Solution**
Implant to cap connection	Regular Diameter (RD) with a Y-TZP implant fixture and a Y-TZP cap/Ti screw	RD with a Y-TZP implant fixture and a Ti cap/screw	Regular Neck (RN)/Wide Neck (WN)/ Narrow Neck CrossFit (NNC)/ Narrow CrossFit (NC)/Regular CrossFit (RC) connections with Titanium-Zirconium (TiZr) or Ti implant fixture and Ti cap/screw
Implant to cap mode of attachment	Screw retained	Screw retained	Screw retained
Diameter	Healing Cap: Ø5.2 mm	Closure Cap: Ø4.8 mm Healing Cap: Ø5.2 mm	Closure & Healing Caps: Ø3.5 mm – 6.5 mm
Overall height	Healing Cap: 6.2, 7.2, and 8.7 mm	Closure Cap: 4.6 mm Healing Cap: 6.2 and 7.2 mm	Closure Cap: 6.2 and 6.8 mm Healing Cap: 8.1, 9.6, and 11.1 mm
Gingival height	Healing Cap: 2.0, 3.0, and 4.5 mm	Closure Cap: 0.5 mm Healing Cap: 2.0 and 3.0 mm	Closure Cap: 0 mm and 0.5 mm Healing Cap: 2.0, 3.0, and 4.5 mm
Sterilization method	End user receives product sterilized per Ethylene oxide to an SAL of 10^{-6}	**Straumann PURE Ceramic Implants** Ethylene oxide to an SAL of 10^{-6} **Closure and Healing Caps** End user receives product sterilized per Irradiation to an SAL of 10^{-6}	End user receives product sterilized per Irradiation to an SAL of 10^{-6}

Table 1 – Comparison of Subject Device with Primary Predicate and Reference Devices

1.7 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Sterilization

A sterilization validation was performed per ISO 11135, Sterilization of healthcare products – Ethylene Oxide – Requirements for development, validation and routine control of a sterilization process for medical devices, using the Half Cycle Overkill Approach. The validation demonstrates that the sterilization process and equipment is capable of reliably and consistently sterilizing the subject device to a minimum Sterility Assurance Level (SAL) of 10^{-6}.

The method used to make the determination that the device meets endotoxin limit specifications is LAL Endotoxin Analysis. The testing limit is 20 EU/device. The testing limit was chosen based on a device that is blood contacting and/or implanted, as outlined in the FDA Guidance *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile*, issued on 21 January 2016. In all cases, the testing was performed on the completed package from a production lot after sterilization.

A transportation study has been performed per ISTA 2A to demonstrate the integrity of the sterile barrier system considering the new sterilization process.

A packaging stability study was performed to demonstrate the integrity of the packaging system and the sterile barrier system after sterilization process via Ethylene Oxide, handling, distribution, transport and storage up to the defined product shelf life.

Biocompatibility Testing

The biological safety of the CI RD Ceramic Healing caps was assessed according to the ISO 10993-1 and tests were conducted to assess the following:

- Cytotoxicity (ISO 10993-5)
- Chemical Characterization (ISO 10993-18)

1.8 Conclusion

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