January 3, 2020

Institut Straumann AG
℅ Jennifer Jackson
Director, Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01801

Re: K192893
Trade/Device Name: Straumann® Ceramic Healing Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 10, 2019
Received: October 11, 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.
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)*

K192893

Device Name:

Straumann® Ceramic Healing Abutments

Indications for Use *(Describe)*

Straumann® Ceramic Healing abutments are indicated to be placed in the patient's mouth at the end of the implant placement to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Healing abutments 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

5 510(k) Summary

5.1 Submitter's Contact Information

Submitter:	Straumann USA, LLC (on behalf of Institut Straumann AG) 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052
	On the behalf of:
	Institut Straumann AG Peter Merian Weg, 12 CH-4002 Basel, Switzerland
Contact Person:	Jennifer M. Jackson, MS Director Regulatory Affairs Phone Number: +1 978 747 2509 Fax Number: +1 978 747 0023
Prepared By & Alternate Contact:	Laure Kuhner Borsenberger Regulatory Affairs Specialist Institut Straumann AG Phone number : +41 61 965 13 89
Date Prepared:	January 2, 2020

5.2 Name of the Device

Trade Names:	Straumann® Ceramic Healing Abutments
Common Name:	Endosseous Dental Implant Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	§872.3630
Device Classification:	II
Product Codes(s):	NHA
Classification Panel:	Dental

5.3 Predicate Device(s)

Primary Predicate:

- K190654 - Straumann PURE Ceramic Healing caps

Reference Devices:

- K162890 - Small Diameter Implant (SDI)
- K190662 - MRI compatibility for existing Straumann dental implant systems

5.4 Device Description

Healing abutments are screwed into the implant to protect the inner configuration in cases of transmucosal healing protocols. They are placed out of occlusion and do not support a prosthetic restoration. The Ceramic Healing Abutments are two-piece devices that feature a ceramic ring in various heights to accommodate individual gingival thickness, with a pre-assembled TAN basal screw. The pre-assembled TAN basal screw is fixed into the ceramic ring and cannot be removed.

5.5 Intended Use

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.

5.6 Indications for Use

Straumann® Ceramic Healing abutments are indicated to be placed in the patient's mouth at the end of the implant placement to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Healing abutments should be used only with suitable implant connections. The healing components are intended to be used up to 6 months.

5.7 Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in Table 1. For clarity in comparison to the reference device K162890, only the relevant part of the indications for use is included in the

comparison table. The reference predicate K190662 is included for reference to MRI compatibility only and is not included in the comparison table below.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE
K Number		K190654	K162890
Indications for Use	Straumann® Ceramic Healing abutments are indicated to be placed in the patient's mouth at the end of the implant placement to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Healing abutments should be used only with suitable implant connections. The healing components are intended to be used up to 6 months.	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® Closure Caps and Healing Abutments are indicated to be placed in the dental implant after placement in the patient's jaw to protect the inner configuration of the implant and to form, maintain and stabilize the soft tissue during the healing process. Closure Caps and Healing Abutments should be used only with the corresponding implant connection.
Material	Y-TZP Ti-6Al-7Nb or TAN (screw)	Y-TZP Titanium Grade 4 (screw)	Titanium Grade 4 Ti-6Al-7Nb or TAN (screw)
Implant to Abutment Connection	Narrow CrossFit® (NC) Regular CrossFit® (RC)	Regular Diameter (RD)	Small CrossFit® (SC)
Diameter or Minor Oval Dimension/ Major Oval Dimension	NC: Ø3.6 & 4.8 mm RC: Ø4.5, 5.0, 6.0, and 6.5 mm	Ø5.2 mm	Closure Cap: Ø2.4 mm Healing Abutments: Ø3.3/4.3 mm Ø3.55/4.86 mm Ø3.6/5.0 mm
Overall Length	NC: 8 to 11 mm RC: 8 to 12 mm	6.2 to 8.7 mm	Closure Cap: 5.8 mm Healing Abutment: 7.0 to 11.5 mm
Gingival Heights	NC: 2.0, 3.5, and 5.0 mm RC: 2.0, 4.0, and 6.0 mm	2.0, 3.0, and 4.5 mm	Closure Cap: 0.5 mm Healing Abutments: 2.0, 3.5, 5.0, and 6.5 mm

Table 1 – Comparison of subject device versus primary predicate and reference devices

5.8 Performance Testing

The subject devices were evaluated for biocompatibility according to ISO 10993-1:2009 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* and the FDA Guidance document "*Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff*". Although the subject device materials are identical to the primary predicate and reference device materials, cytotoxicity and chemical characterization tests were performed due to differences in the manufacturing process. These tests were conducted according to ISO 10993-5, 10993-12, 10993-17 and 10993-18.

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.

5.9 Conclusion

The documentation submitted in this premarket notification demonstrates the Straumann® Ceramic Healing Abutments are substantially equivalent to the primary predicate and reference devices.