September 24, 2020

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

Re: K201051
Trade/Device Name: Straumann® BoneCeramic
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone grafting material
Regulatory Class: Class II
Product Code: LYC
Dated: August 23, 2020
Received: August 25, 2020

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)*

K201051

Device Name:

Straumann® BoneCeramic

Indications for Use *(Describe)*

Straumann® BoneCeramic is indicated for filling and/or augmenting the following intraoral/maxillofacial osseous defects:

- Intrabony periodontal osseous and furcation defects
- Augmentation of bony defects of the alveolar ridge
- Filling tooth extraction sites
- Sinus elevation grafting

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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K201051 – Traditional 510(k) Submission

Straumann® BoneCeramic

510(k) Summary

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 of Regulatory Affairs and Quality Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023
Prepared By:	Christelle Gerspach-Gasser Senior Lead RA Biomaterials Institut Straumann AG Phone number: +41 61 965 1666
Date Prepared:	September 23, 2020

5.2 Name of the Device

Trade Names:	Straumann® BoneCeramic
Common Name:	Bone Grafting Material
Classification Name:	Bone Grafting Material, Synthetic
Regulation Number:	§872.3930
Device Classification:	II
Product Code(s):	LYC
Classification Panel:	Dental

5.3 Predicate Device(s)

Primary Predicate:

- K040646 - Straumann Granules

5.4 Device Description

Straumann® BoneCeramic is a fully synthetic bone graft substitute of medical grade purity in particulate form composed of biphasic calcium phosphate. It consists of a mixture of 60% hydroxyapatite (HA), which is 100% crystalline, and of 40% of the beta form of tricalcium phosphate (beta-TCP). BoneCeramic is 90% porous with interconnected pores of 100-500 microns in diameter. It is osteoconductive and gradually resorbed and replaced by vital bone during bone remodeling.

BoneCeramic is available in two granule sizes: 400-700 µm diameter and 500-1000 µm diameter and in three different filling volumes: 0.25g, 0.5g and 1.0g. It is delivered sterile.

5.5 Intended Use

Straumann® BoneCeramic is intended to be used for filling and/or augmenting intraoral/maxillofacial osseous defects.

5.6 Indications for Use

Straumann® BoneCeramic is indicated for filling and/or augmenting the following intraoral/maxillofacial osseous defects:

- Intrabony periodontal osseous and furcation defects
- Augmentation of bony defects of the alveolar ridge
- Filling tooth extraction sites
- Sinus elevation grafting

5.7 Technological Characteristics

The chemical composition, structure and indications for use of the subject device are identical to those of the predicate device. The only difference between the two relies in the different primary packaging utilized for the subject device. A comparison of the technological characteristics between the subject device and the primary predicate is provided in Table 1.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE
K Number	K201051	K040646
Indications for use	Straumann® BoneCeramic is indicated for filling and/or augmenting the following intraoral/maxillofacial osseous defects: • Intrabony periodontal osseous and furcation defects • Augmentation of bony defects of the alveolar ridge • Filling tooth extraction sites • Sinus elevation grafting	Straumann Granules are indicated for filling and/or augmenting intraoral /maxillofacial osseous defects, such as: • Intrabony periodontal osseous defects • Furcation defects • Augmentation of bony defects of the alveolar ridge • Filling of tooth extraction sites and sinus elevation grafting.
Material (Chemical composition)	Hydroxyapatite (60%) and beta-tricalcium phosphate (40%)	Hydroxyapatite (60%) and beta-tricalcium phosphate (40%)
Structure / Porosity	Matrix consisting of interconnected pores (90% porosity), the size of the pores lies within a range of approx. 100 – 500 microns in diameter.	Matrix consisting of interconnected pores (90% porosity), the size of the pores lies within a range of approx. 100 – 500 microns in diameter.
Particle sizes	400 – 700 µm and 500 – 1000 µm	400 – 700 µm and 500 – 1000 µm
Packaging	Sterile barrier system and protective packaging: 1) Primary packaging: polystyrene jar closed with a polypropylene cap 2) Secondary packaging: PETG blister sealed with a Tyvek lid (sterile barrier) 3) Tertiary packaging: cardboard box	Sterile barrier system and protective packaging: 1) Primary packaging: PET blister with PE sealing layer 2) Secondary packaging: PET blister sealed with a Tyvek lid (sterile barrier) 3) Tertiary packaging: cardboard box
Sterilization	Gamma irradiation	Gamma irradiation
Biological characteristics	Biocompatible	Biocompatible

Table 1 – Comparison of subject device versus predicate device

5.8 Performance Testing

Chemical characterization and biological testing were conducted according to the ISO standard for the biological evaluation of medical devices, ISO 10993, and to the FDA guidance document for this standard (FDA 2016, *Use of International Standard ISO-10993*). The new packaging material has been assessed in accordance to the above-mentioned standard and the biocompatibility of the device was confirmed. Furthermore, the packaging process and shelf life of the device have been validated per ISO 11607 and ASTM F1980.

The sterilization process for the subject device as indicated in the labeling has been validated according to ISO 11137 "*Sterilization of health care products – Radiation", part 1 and 2.* The

devices will not be marketed as non-pyrogenic. Pyrogenicity information provided is based on FDA Guidance on “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile, issued on 21 January 2016.” The method used to determine the device meets pyrogen limit specifications is LAL Endotoxin Analysis on every batch with a testing limit of 20 EU/device, based on a blood contacting and implanted device.

Device marketing and complaint history and review of the relevant clinical literature was provided. Over a period of 13.5 years, the overall complaint rate based on individual units sold globally for the subject devices was <0.05%. The review of the relevant clinical literature included 18 clinical publications across the relevant indications for use: intrabony osseous and furcation defects, augmentation of bony defects of the alveolar ridge, filling of tooth extraction sites, and sinus elevation grafting. The device marketing and complaint history and review of the relevant clinical literature provided demonstrates successful product use.

5.9 Conclusion

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