October 19, 2018

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

Re: K173594
Trade/Device Name: Straumann® cerabone®
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: September 17, 2018
Received: September 20, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

for Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173594

Device Name
Straumann® cerabone®

Indications for Use *(Describe)*
Straumann® cerabone® is used in the following intra-oral surgical procedures:
- Alveolar ridge augmentation/ reconstruction
- Filling of defects after root resection and apicoectomy
- Filling alveoli after tooth extraction
- Sinus elevation

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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510(k) Summary

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

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Date Prepared: October 19, 2018

Product Code(s): NPM 21 CFR 872.3930

Device Class: II 21 CFR 872.3930

Classification Panel: Dental Devices

Classification Name: Bone Grafting Material

Common Name: Bone Grafting Material

Proprietary Name: Straumann® cerabone®

Predicate Device(s): K122894 Geistlich Bio-Oss

Device Description: Straumann® cerabone® is a xenogeneic hydroxyapatite ceramic for implantation into a vital bone bed during intra-oral surgical procedures. It is manufactured from bovine cancellous bone in a high temperature sintering process lasting several hours at temperatures of up to 1250°C. This high temperature process results in all organic components being eliminated so that the risk on occurrence of allergic side effects or the occurrence of rejection reactions is reduced.

Straumann® cerabone® is made of over 95% of Pentacalcium-hydroxy-[tri]-phosphate $Ca_5(PO_4)_3(OH)$ (Hydroxyapatite).

Due to the animal-derived starting material, Straumann® cerabone® possesses an interconnected macro- and micro-porous structure that strongly resembles human bone structure. The macroporosity lies within a range of 65–80 vol % and the pore size lies within a range of approximately 100 – 1,500 µm. After implantation, the particles serve as an osteoconductive guide rail for new bone formation. The grafting material has high stability over several years with only minor signs of graft resorption.

Straumann® cerabone® acts as a scaffold for stabilization and the deposition of new bone matrix. Due to porosity and rough surface structure, Straumann® cerabone® facilitates cell adhesion. Subsequently, bone formation starts by deposition of primarily not yet mineralized bone matrix. Within a time period of six to eight months following implantation, the graft is integrated into the newly formed bone matrix.

Straumann® cerabone® is biocompatible and packed in a triple sterile barrier system consisting of a glass vial and two outer blisters and subject to sterilization by gamma-irradiation.

Straumann® cerabone® is offered in two particle size ranges (0.5 – 1.0 mm and 1.0 – 2.0 mm) and various pack sizes (0.5, 1.0, 2.0 and 5.0 cc).

Art. No.	Article Name
BS-1510	Straumann® cerabone®, 0.5 – 1.0 mm, 1 × 0.5 cc
BS-1511	Straumann® cerabone®, 0.5 – 1.0 mm, 1 × 1.0 cc
BS-1512	Straumann® cerabone®, 0.5 – 1.0 mm, 1 × 2.0 cc
BS-1515	Straumann® cerabone®, 0.5 – 1.0 mm, 1 × 5.0 cc
BS-1520	Straumann® cerabone®, 1.0 – 2.0 mm, 1 × 0.5 cc
BS-1521	Straumann® cerabone®, 1.0 – 2.0 mm, 1 × 1.0 cc
BS-1522	Straumann® cerabone®, 1.0 – 2.0 mm, 1 × 2.0 cc
BS-1525	Straumann® cerabone®, 1.0 – 2.0 mm, 1 × 5.0 cc

Indications For Use: Straumann® cerabone® is used in the following intra-oral surgical procedures:

- Alveolar ridge augmentation/ reconstruction
- Filling of defects after root resection and apicoectomy
- Filling alveoli after tooth extraction
- Sinus elevation

Technological Characteristics: The subject and the predicate device are both sterile, biocompatible porous bone mineral materials for use in the same intra-oral surgical procedures.

The subject and predicate devices are based on the following same technological elements:

- Pure cancellous bovine bone mineral (free from organic compounds)
- Rough surface structure, interconnecting macro- and micro pores
- Scaffold provision as mode of action
- Same sterilization method and shelf life

The comparison between the features of the subject device and the predicate are provided in the table below. The Indications for Use for the subject device are a subset of the Primary Predicate Indications for Use.

Feature	**Subject Device** Straumann® cerabone®	**Primary Predicate Devices** Geistlich Bio-Oss K122894
Indications for use	Straumann® cerabone® is used in the following intra-oral surgical procedures: • Alveolar ridge augmentation/ reconstruction • Filling of defects after root resection and apicoectomy • Filling alveoli after tooth extraction • Sinus elevation	Geistlich Bio-Oss® is indicated for: • Augmentation or reconstructive treatment of the alveolar ridge • Filling of intrabony periodontal defects • Filling of defects after root resection, apicoectomy and cystectomy • Filling of extraction sockets to enhance preservation of the alveolar ridge • Elevation of the maxillary sinus floor • Filling of periodontal defects in conjunction with products identified for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR); and • Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

Feature	**Subject Device** Straumann® cerabone®	**Primary Predicate Devices** Geistlich Bio-Oss K122894
Material	xenogenic hydroxyapatite (calcium phosphate) ceramic manufactured from cancellous (spongiosa) bovine bone	xenogenic hydroxyapatite (calcium phosphate) ceramic manufactured from cancellous (spongiosa) bovine bone
Origin	Femoral heads of cattle	Femoral heads of cattle
Form	Granules	Granules
Composition	- Hydroxyapatite (Pentacalcium-hydroxy-[tri]-phosphate Ca5(PO4)3(OH)) (≥95%) - ≤2.5% other calcium phosphates (traces of calcium carbonate (CaO3) (<0.1%)) - No water (0%) - No organic components (0%)	- Hydroxyapatite (Pentacalcium-hydroxy-[tri]-phosphate Ca5(PO4)3(OH)) (93.6%), - Calcium carbonate (CaO3) (3,4%) - Water (3%) - No organic components (0%)
Appearance (dry state)	Whitish up to beige	Whitish
Structure / Density	Matrix possessing an interconnected macro- and micro-porous structure.	Matrix consisting of interconnected macro- and micropores, highly porous with a large inner surface area.
Specifications / Granules sizes	Granule sizes 0.5 – 1.0 mm 1.0 – 2.0 mm	Granule sizes 0.25 – 1.0 mm 1.0 – 2.0 mm
Packaging & Sterilization	Single use, triple sterile barrier system, terminally gamma sterilized by gamma irradiation	Single use, double sterile barrier system, terminally gamma sterilized by gamma irradiation
Sterilization	Gamma-irradiation	Gamma-irradiation
Shelf life	3 years	3 years

Performance Data: The following performance data were provided in support of the substantial equivalence determination

Sterilization and Shelf Life:

- Validation of sterilization process per ISO 11137-1
- Validation of shelf life per ASTM F1980

Biocompatibility Testing:

- Biocompatibility testing per ISO 10993-1 and the following:
  - Cytotoxicity per ISO 10993-5
  - Sensitization per ISO 10993-10
  - Irritation per ISO 10093-10
  - Subchronic Toxicity per ISO 10993-11
  - Genotoxicity per ISO 10993-3
  - Implantation per ISO 10993-6

Performance Testing – Bench:

- Physicochemical and material characterization per ASTM F 1185-03 and ASTM F 1581-99
- Viral inactivation demonstrated through validation of manufacturing steps, and the assessment of the potential pathogenic burden, quality management system in place. The Zoonosis assessment demonstrated that the validated manufacturing processes are sufficient to ensure a reduction of viral burden in accordance with the recommendation of the FDA recognized standard ISO 22442-3 and are sufficient for the demonstration of substantial equivalence to the predicate device.

Performance Testing – Animal:

- The osteoconductive capacity of Straumann® cerabone® in intra-oral defects was assessed in a kinetic study in minipigs with comparison to the primary predicate Bio-Oss®. The performance of cerabone was equivalent to the primary predicate device Bio-Oss.

Performance Testing – Clinical:

- A review of the clinical literature was performed. The reviewed literature supports the use of Straumann® cerabone® in the proposed Indications for Use.

Conclusions: Following assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate device.