DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Institut Straumann Ag
% Jennifer Jackson
Director Of Regulatory Affairs And Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

March 7, 2017

Re: K162311
Trade/Device Name: Straumann PrefGel
Regulation Number: 21 CFR None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: KJJ
Dated: February 5, 2017
Received: February 7, 2017

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. 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,

Susan Runner DDS, MA

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: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*

Device Name

Straumann® PrefGel®

Indications for Use *(Describe)*

Straumann PrefGel is intended for topical application onto exposed root surfaces during periodontal surgery in order to remove the smear layer.

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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K162311
510(k) Summary

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:	Jennifer M. Jackson, MS Director of Regulatory Affairs and Quality +1 (978) 747-2509
Prepared By:	Christopher Klaczyk Head of North American Regulatory Affairs Institut Straumann AG +41 61 965 1260
Date Prepared:	March 7, 2017
Product Code(s):	KJJ
Device Class:	Unclassified (pre-amendments device)
Classification Reg.:	N/A
Classification Panel:	Dental
Classification Name:	Cleanser, root canal
Proprietary Name:	Straumann® PrefGel®
Predicate Device(s):	K063812, Straumann® PrefGel® (Institut Straumann AG)
Reference Device(s)	None
Device Description:	Straumann PrefGel is a neutral EDTA formulation intended for topical application onto exposed root surfaces during periodontal surgery in order to remove the smear-layer. Mechanical debridement of a root surface inevitably produces a smear-layer, which in turn may prevent or retard periodontal healing. Exposure of collagen fibers may be important for linking fibrin in the blood clot to the root surface. Clinical studies with PrefGel have demonstrated the ability to remove the smear-layer and to expose the collagenous matrix of dentin surfaces.

Indications For Use Straumann PrefGel is intended for topical application onto exposed root surfaces during periodontal surgery in order to remove the smear layer.

Intended Use: PrefGel has been shown to effectively remove the smear-layer. PrefGel has also been shown to produce a fibrillar collagenous meshwork on the exposed and conditioned root surface by selective removal of mineral.

Materials: Edetate disodium [EDTA] 2 H_2O 24% neutral in carboxymethyl cellulose (CMC) gel

Technological Characteristics: This submission describes an alternate packaging system for the Straumann® PrefGel® product. We have proposed changes to the primary, secondary and tertiary packaging. The therapeutic material (EDTA 2 H_2O 24% neutral in CMC gel) remains unchanged, as does the Indications For Use. The table that follows provides a side-by-side comparison of the subject device to the predicate device.

Performance Data: Test data to support the evaluation of the Straumann® PrefGel® product has been included directly or by reference as follows:

- Clean room qualification per ISO14644-1.
- Secondary packaging equipment qualification consistent with the ISO 11607 series of standards.
- Syringe filling labeling and assembly process validation.
- Transport validation per ISTA 2A to assure proposed packaging adequately protects the product.
- Biocompatibility assessment per ISO 10993-1, ISO 10993-5 and ISO 10993-18.
- Ethylene oxide sterilization validation per ISO 11135 and ISO 11737-2.
- Ethylene oxide residuals testing per ISO 10993-7.
- Simulated use validation to assure that clinicians will be able to properly use the proposed Tip Cap.

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 predicate devices.

Feature	Primary Predicate Straumann® PrefGel® (K063812)	Subject Device Straumann® PrefGel®	Equivalence Discussion
Indications For Use	Straumann PrefGel is intended for topical application onto exposed root surfaces during periodontal surgery in order to remove the smear layer.	Straumann PrefGel is intended for topical application onto exposed root surfaces during periodontal surgery in order to remove the smear layer.	**Identical Indications For Use** The changes to the primary (syringe), secondary (blister) and tertiary (Shelf box) packaging of the subject devices do not result in a modification in the Indications For Use.
Therapeutic Material	0.6 ml of edetate disodium [EDTA] 2 H_2O 24% neutral in carboxymethyl cellulose (CMC) gel	0.6 ml of edetate disodium [EDTA] 2 H_2O 24% neutral in carboxymethyl cellulose (CMC) gel	**Identical Therapeutic Material** The changes to the primary (syringe), secondary (blister) and tertiary (Shelf box) packaging of the subject devices do not affect the formulation of the therapeutic material contained within the primary package. Because the therapeutic material is unchanged, the Indications For Use have not change.
Primary Package	Syringe Barrel (COC, TOPAS® 6013) Siliconization: (NuSil MED 361 & MED1-4158) Tip Cap (bromobutyl rubber) Plunger (bromobutyl rubber) Plunger Rod (polypropylene)	Syringe Barrel (Type I borosilicate glass) Siliconization: (Dow Corning Medical Fluid 360) Tip Cap (West Pharma poly-isoprene rubber) Plunger (West Pharma elastomer) Plunger Rod (polystyrene) Back Stop (polypropylene)	**Equivalent Primary Package** The subject device will now use a glass syringe with compatible plunger components. The predicate uses a plastic syringe with compatible plunger components. In both cases the product contacting materials have been shown to be compatible with the therapeutic material. The addition of a back stop is specific to the use of the glass syringe and replicates functionality that is molded into the predicate plastic syringe.

Feature	Primary Predicate Straumann® PrefGel® (K063812)	Subject Device Straumann® PrefGel®	Equivalence Discussion
Secondary Package	Thermoformed Tray (PETG) Lid Stock (Medical Paper)	Thermoformed Tray (PETG) Lid Stock (Tyvek 1073B)	**Equivalent Secondary Package** The blister tray is the same material; only the form has changed. Both the subject and predicate lid stocks are accepted for sterile barrier applications. The change to Tyvek 1073B adds additional durability and is consistent with other products produced at Biora AB.
Tertiary Package	Bleached and printed cardboard	Bleached and printed cardboard	**Equivalent Tertiary Package** The material used for the tertiary protective packaging (i.e. shelf box) is the same. The package configuration has been changed to accept the larger secondary blister package. The packaging has been verified to adequately protect the product.
Product Configurations	5-Pack: Five PrefGel Trays Five Sterile Blunt Cannulae	5-Pack: Five PrefGel Trays Five Sterile Blunt Cannulae	**Identical Product Configuration** The changes to the primary (syringe), secondary (blister) and tertiary (Shelf box) packaging of the subject devices have not resulted in a change to the product configurations offered. The blunt cannulae used with the subject devices are the same ones used for the predicate devices.
Sterility – Primary	Cleanroom environment, sterilization by heat (121°C) and aseptic technique.	Cleanroom environment, sterilization by heat (121°C) and aseptic technique.	**Identical Sterilization of Primary Package** The subject devices continue to be produced in the same clean rooms, sterilizers and aseptic conditions as the predicate devices through the primary packaging (syringe) stage.

Feature	Primary Predicate Straumann® PrefGel® (K063812)	Subject Device Straumann® PrefGel®	Equivalence Discussion
Sterility – Secondary	Ethylene oxide gas to a Sterility Assurance Level (SAL) of 10^{-6}	Ethylene oxide gas to a Sterility Assurance Level (SAL) of 10^{-6}	**Identical Sterility of Secondary Package** The subject devices have been adopted into the same EtO sterilization cycle as the predicate device. This cycle has been validated to an SAL of 10^{-6}. New clean room facilities have been built to accommodate the secondary packaging operations internal to Biora AB—this operation is no longer out-sourced.