DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 3, 2017

Kerr Corporation
% Mohammad Ansari
Regulatory Affairs Specialist II
Sybron Dental Specialties
1717 W. Collins Ave.
Orange, California 92867

Re: K162536
Trade/Device Name: Gingiknit+, Gingibraid+, Gingibraid+ Shortcut, and Unibraid+ Impregnated Aluminum Potassium Sulfate Retraction Cord
Regulation Number: 21 CFR
Regulation Name: (Not A Regulation) Retraction Cord
Regulatory Class: Unclassified
Product Code: MVL
Dated: January 6, 2017
Received: January 9, 2017

Dear Mohammad Ansari:

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,

Michael J. Ryan -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162536

Device Name

GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium

Indications for Use *(Describe)*

GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord are for the temporary retraction of the gingival margins and hemostasis procedures. The Retraction Cord is placed in the sulcus to displace the gingival tissues for a short period prior to making an impression or for other restorative procedures.

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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K162536

510(k) SUMMARY

1. Submitter Information**:**

Sybron Dental Specialties
1717 W. Collins Ave.
Orange CA, 92867

Contact Person: Mohammad Saad Ansari
Telephone Number: 909-962-5644
Fax Number: 909-962-5694

Date Prepared: January 27, 2017

2. Device Name:

- Proprietary Name: GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord

- Classification Name: Retraction Cord
- CFR Number: 872.3275
- Device Class: Unclassified
- Product Code: MVL

3. Predicate Device:

GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord are substantially equivalent to the legally marketed device(s) Premier Dental Products Co.'s Knit-Pak+, K132526, cleared on November 26, 2013.

4. Description of Device:

Dental retraction materials are used to aid in creating accurate impressions of sub-gingival margins by temporary gingival displacement, and control of sulcular seepage and hemorrhage. Cords are impregnated with Aluminum Potassium Sulfate. The braided GingiBraid+ and the knitted GingiKnit+ are made of cotton fiber with a different color strand running through the cord for identification of the diameter. Retraction Cords have a yellow background color for medicament identification. The usage is inherently of transient nature. Typical exposure time is less than five minutes. The braided and knitted cord configurations are available in different sizes to fit the sulcus. There have been no prior submissions on the subject product line.

5. Intended Use:

The intended use of GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord is for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of a rubber dam.

6. Indications for Use:

GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord are for the temporary retraction of the gingival margins and hemostasis procedures. The Retraction Cord is placed in the sulcus to displace the gingival tissues for a short period prior to making an impression or for other restorative procedures.

7. Description of Substantial Equivalence:

Technological Characteristics

The designs of GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord are similar to the predicate KnitPak+ (K132526). The braided or knitted cotton also contains a surfactant and the chemical Aluminum Potassium Sulfate for hemostasis. The braided retraction material is made of cotton fiber and a solid cord that provides a strong physical retraction and will not split or collapse in the sulcus. It can be used with any type of packing instrument. The knitted retraction cord is constructed by knitting many tiny loops together to form a long interlocking chain that places easily without fraying or memory. The GingiKNIT+ Aluminum Potassium Sulfate Retraction Cord conforms to the sulcus with a gentle, outward force. The knitted retraction cord will cut cleanly if touched by a high-speed cutting instrument.

8. Non-Clinical Performance Data

Non-clinical performance data included Stability, Cutting Test, Water Contact Test and Biocompatibility testing.

The following standards were utilized for the non-clinical performance testing:

- ISO 10993-1: 2009 Biological evaluation of medical devices
- ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: Tests for in Vitro Cytotoxicity

Table 8.1: Predicate and Proposed Device Comparison Table

Element	**Predicate Knit-Pak+**	**Proposed GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord**
510(k)	K132526	K162536
510(k) Sponsor	Premier Dental Company Products	Sybron Dental Specialties
Target Users	Licensed dental professionals	Licensed dental professionals

Element	Predicate Knit-Pak+	Proposed GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord
Intended Use	The intended use of KnitPak+ is for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of a rubber dam.	The intended use of GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord is for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of a rubber dam.
Indications for Use	Knit-Pak+, a prescription-only, Aluminum Chloride Hexahydrate impregnated cord is used for temporary chemo-mechanical retraction of gingival tissues and hemostasis of the gingival margin around the tooth. It is intended for accurate and enhanced results when acquiring dental impressions, for cavity preparation or wherever hemostasis and retraction is required.	GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord are for the temporary retraction of the gingival margins and hemostasis procedures. The Retraction Cord is placed in the sulcus to displace the gingival tissues for a short period prior to making an impression or for other restorative procedures.
Common Name	Retraction Material	Retraction Material
Classification Name	None	None
Class	Unclassified	Unclassified
Product Code	MVL	MVL
Astringent/Hemostatic Agent	Aluminum Chloride	Aluminum Potassium Sulfate
Additional Ingredients	Cotton (others unknown)	Cotton, Silwet (surfactant)
Contact Time	Less than 5 minutes	Less than 5 minutes
Material Compatibility	Biocompatibility meets requirements	Biocompatibility meets requirements
Configurations	Knitted Cord	Retraction Cord available as: Knitted, Braided, Braided with ShortCut, Precut Single Unit Dose

Element	Predicate Knit-Pak+	Proposed GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord
Amount	100 inches (254 cm)	6 foot total or 2 inch single unit
Packaging	Bottles	Bottles Specialized ShortCut+ System Single Unit Dose 2 inch

9. Clinical Performance Data

Clinical performance testing has not been performed for GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord.

10. Conclusion as to Substantial Equivalence

The subject device and its predicate KnitPak+ differ in their configuration and hemostatic agent. However, the technological characteristics of the subject GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord are virtually identical to the predicate, KnitPak+ (K132526), and both devices have the same device intended use. Both devices have retraction as their primary function. The subject device uses the chemical Aluminum Potassium Sulfate while the predicate uses Aluminum Chloride. Results of nonclinical testing demonstrate that the proposed GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction cord has similarities in select performance characteristics as compared to the predicate. Any noted differences in technological characteristics between the proposed and predicate products do not raise new questions of safety or effectiveness.

The subject deviceis substantially equivalent to the predicate KnitPak+ (K132526), based on design, performance, biocompatibility testing, and the intended use.