DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 13, 2017

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

Re: K162164
Trade/Device Name: GingiKnit+, GingiBraid+, and Shortcut with GingiBraid+ Non-Impregnated Retraction Cord
Regulation Number: None
Regulation Name: Retraction Cord
Regulatory Class: Unclassified
Product Code: MVL
Dated: December 15, 2016
Received: December 19, 2016

Dear Mohammad Saad 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)*
K162164

Device Name

GingiKnit+, GingiBraid+, and Shortcut with GingiBraid+ Non-Impregnated Retraction Cord

Indications for Use *(Describe)*

GingiKnit+, GingiBraid+, and Shortcut with GingiBraid+ Non-Impregnated Retraction Cord are for the temporary retraction of the gingival margin. The Retraction Cord is placed in the sulcus to displace gum tissue for a small period of time in dental 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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K162164

510(k) SUMMARY

1. Submitter Information**:**

Sybron Dental Specialties
1717 W. Collins Ave.
Orange CA, 92687

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

Date Prepared: January 9, 2017

2. Device Name:

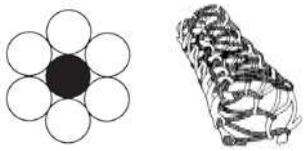
- Proprietary Name: GingiKnit+, GingiBraid+, and GingiBraid+ ShortCut Non-Impregnated Retraction Cord
- Classification Name: Retraction Cord
- CFR Number: 872.3275
- Device Class: Unclassified
- Product Code: MVL

3. Predicate Device:

GingiKnit+, GingiBraid+, and GingiBraid+ ShortCut Non-Impregnated Retraction Cord are substantially equivalent to the legally marketed device(s) Microscopy, Division of Neo-Flo, Inc.'s Quicknit Cord, K131799, product code MVL, cleared on January 16th, 2014.

4. Description of Device:

GingiKnit+, GingiBraid+, and GingiBraid+ ShortCut Non-Impregnated Retraction Cord are dental retraction materials used to aid accurate impressions of sub-gingival margins by temporary gingival displacement, control sulcular seepage and control hemorrhage. Non-impregnated retraction materials are to be used in combination with an astringent/hemostatic solution of choice. The usage is inherently of transient nature. Typical exposure time is less than five minutes. The non-impregnated retraction materials consists only of braided or knitted cotton yarn soaked with an aqueous surfactant solution and then dried to facilitate absorption of medicament containing retraction solution of dentist's choice into the cotton cord. The braided and knitted cord configurations are available in different sizes to fit the sulcus.



5. Intended Use:
Retraction Cords are for the temporary retraction of the gingival margins and hemostasis procedures.

6. Indications for Use:
GingiKnit+, GingiBraid+, and GingiBraid+ ShortCut Non-Impregnated Retraction Cord are for the temporary retraction of the gingival margin. The Retraction Cord is placed in the sulcus to displace gum tissue for a small period of time in dental procedures.

7. Description of Safety and Substantial Equivalence:
Technological Characteristics
The designs of GingiKnit+, GingiBraid+, and GingiBraid+ ShortCut Non-Impregnated Retraction Cord are similar to the predicate Quicknit Cord (K131799). They are all Non-Impregnated Retraction Cord products. Neither product contains an additional hemostatic chemical agent. The proposed device includes a surfactant wetting agent.

8. Non-Clinical Performance Data
Non-clinical performance data included 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 Quicknit Cord	Proposed GingiKnit+, GingiBraid+, and ShortCut with GingiBraid+ Non-impregnated Cord
510(k)	K131799	K162164
Target Users	Licensed dental professionals	Licensed dental professionals
Intended Use	Retraction Cords are for the temporary retraction of the gingival margins and hemostasis procedures.	Retraction Cords are for the temporary retraction of the gingival margins and hemostasis procedures.
Indications for Use	Quicknit Cord is unimpregnated cord for the temporary retraction of the gingival margin. The gingival retraction cord is placed in the sulcus (between the gum tissue and your tooth structure) to displace the gum tissue for a small period of time in dental procedures.	GingiKnit+, GingiBraid+, and GingiBraid+ ShortCut Non-Impregnated Retraction Cord are for the temporary retraction of the gingival margin. The Retraction Cord is placed in the sulcus to displace gum tissue for a small period of time in dental procedures.

Element	Predicate Quicknit Cord	Proposed GingiKnit+, GingiBraid+, and ShortCut with GingiBraid+ Non-impregnated Cord
Common Name	Retraction Material	Retraction Material
Classification Name	None	None
Class	Unclassified	Unclassified
Product Code	MVL	MVL
Astringent/Hemostatic Agent	None	None
Contact Time	Unknown	Less than 5 minutes
Material Composition	100% Cotton	Cotton and surfactant
Material Compatibility	Biocompatibility meets requirements of ISO 10993	Biocompatibility meets requirements of ISO 10993
Configurations	Knitted	Knitted, Braided, Braided with ShortCut

9. Clinical Performance Data

Clinical performance testing has not been performed for GingiKnit+, GingiBraid+, and GingiBraid+ ShortCut Non-Impregnated Retraction Cord.

10. Conclusion as to Substantial Equivalence

The proposed device and the predicate Quicknit Cord (K131799) differ in their configuration, packaging, and delivery method. Neither the predicate nor the proposed devices are impregnated with hemostatic solutions and are primarily composed of cotton material. The proposed device includes a surfactant wetting agent to aid in soaking. The proposed GingiKnit+, GingiBraid+, and GingiBraid+ ShortCut Non-Impregnated Retraction Cord have similarities in select performance characteristics as compared to the predicate. Results of nonclinical testing demonstrate that any noted differences in technological characteristics between the proposed and predicate products to not raise new questions of safety and effectiveness. The proposed product line is substantially equivalent to the predicate Quicknit Cord (K131799) based on design, performance, biocompatibility testing, indications for use and the intended use.