DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Kerr Corporation
c/o Mohammad Saad Ansari
Regulatory Affairs Specialist II
Sybron Dental Specialties
1717 W. Collins Ave.
Orange, California 92867

August 8, 2017

Re: K162948
Trade/Device Name: Styptin, Hemogin-L, Hemodettes, and GingiGEL Aluminum Chloride Impregnated Retraction Cord/Materials
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MVL
Dated: July 25, 2017
Received: July 26, 2017

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,

Mary S. Runner -S

for
Lori Wiggins
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)*
K162948

Device Name
Styptin, Hemogin-L, Hemodettes, and GingiGEL Aluminum Chloride impregnated Retraction Cord/ Materials

Indications for Use *(Describe)*
Aluminum Chloride impregnated retraction material 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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510(k) SUMMARY for Styptin, Hemogin-L, Hemodettes, and GingiGEL Aluminum Chloride impregnated Retraction Materials K162948

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Applicant Information:

Sybron Dental Specialties
1717 W. Collins Ave.
Orange CA, 92687 USA
Fax: 909-962-5694

Correspondent Contact Information:

Mohammad Saad Ansari
Regulatory Affairs Specialist II
Tel:714-516-7793
Fax:909-962-5694

Date Prepared: August 7, 2017

B. Subject Devices:

Table 5.1: Proposed Devices- Aluminum Chloride Impregnated Retraction Cords/ Materials

Trade Name	*Styptin, Hemogin-L, Hemodettes, and GingiGEL* Aluminum Chloride impregnated Retraction Cord/ Materials
Regulation Number	Not Applicable
Common Name	Retraction Cord
Device Class	Unclassified
Product Code	MVL
Panel	Dental

C. Predicate Devices:

Table 5.2: Predicate Devices: Primary and Reference

Elements	Primary Predicate	Reference Predicate	Reference Predicate
Trade Name	GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Retraction Cord	*Expa-syl*	*ViscoStat Clear* (Manufacturer recommends using in conjunction with non-impregnated retraction cord.)
510(k) Sponsor	Sybron Dental Specialties	Sybron Dental Specialties	Ultradent Products Inc. / OraTech LLC
510(k) #	K162536 (February 3, 2017)	K050180 (February 11, 2005)	K123215 (February 5, 2013)
Regulation Number	Not Applicable	Not Applicable	Not Applicable
Common Name	Retraction Material	Retraction Material	Retraction Material
Device Class	Unclassified	Unclassified	Unclassified
Product Code	MVL	MVL	MVL
Panel	Dental	Dental	Dental

D. Description of Device:

As part of a tissue management procedure, Styptin, Hemogin-L, Hemodettes, and GingiGEL are aluminum chloride containing astringent/ hemostatic solutions and gels that are intended to be supplied with gingival retraction cord or cotton pellets that are either pre-impregnated or for end-user impregnation by soaking the cords or cotton pellets in these solutions. The aluminum chloride impregnated retraction material is then packed into the sulcus to temporarily displace gingival tissue to expose the sub-gingival margins and control sulcular seepage and hemorrhage for impression taking and other restorative treatments. The supplied retraction material is available as an aqueous aluminum chloride solution or gel and either unit-dose 2”-pieces of braided cotton cord, braided cotton-polyester cord, or unit-dose cotton pellets.

Table 5.3: Design Description: Subject Device – Configuration, Component Sizes by Part Number, Exposure Time and Shelf Life

Proposed Device Name	Configuration	Part Number and Component Sizes	Time of Exposure During Treatment	Shelf Life and Storage Conditions
Styptin	Pre-Treated and Braided Cotton Fiber Non-Impregnated Retraction Cord and Aqueous 20% Aluminum Chloride Solution	Retraction Cord: Individual, 2-inch, pieces of retraction cord in the following sizes*: • Size 0n • Size 1n • Size 2n Aqueous $AlCl_3$ Solution: • 13156: 15 mL • 13157: 30 mL	< 5 minutes	3 years at room temperature
Hemogin-L	Pre-Treated and Braided Cotton Fiber Non-Impregnated Retraction Cord and Aqueous 25% Aluminum Chloride Solution	Retraction Cord: Individual, 2-inch, pieces of retraction cord in the following sizes*: • Size 0n • Size 1n • Size 2n Aqueous $AlCl_3$ Solution: • 13057: 10 mL • 13058: 20 mL • 13052: 35 mL	< 5 minutes	3 years at room temperature

Proposed Device Name	Configuration	Part Number and Component Sizes	Time of Exposure During Treatment	Shelf Life and Storage Conditions
Hemodettes	Pre-Treated and Pre-Soaked Cotton Pellets and Aqueous, Buffered 20% Aluminum Chloride Gel in unit dose plastic cups	<u>Retraction Cord (Cotton Pellets) and Aqueous $AlCl_3$ gel:</u> 2-Cotton Pellets and Buffered, Aqueous $AlCl_3$ Gel in Each Unit Dose, Plastic Cup: • 13150	< 5 minutes	2 years at room temperature
GingiGEL	Pre-Treated and Braided Polyester and Cotton Fiber Impregnated Retraction Cord with Aqueous 20% Aluminum Chloride Gel	<u>Retraction Cord and Aqueous $AlCl_3$ Solution:</u> • 13165: Size 1 (Small) • 13166: Size 2 (Medium) Pre-Treated and Impregnated Retraction Cord (6 feet in length) and Aqueous $AlCl_3$ Solution are Stored in the Same Bottle.	< 5 minutes	3 years at room temperature

*All 3 sizes are included in each finished good part number.

E. Intended Use:

Retraction Cords are for the temporary retraction of the gingival margins and hemostasis procedures.

F. Indications for Use:

Aluminum Chloride impregnated retraction material 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.

G. Description of Safety and Substantial Equivalence:

Technological Characteristics

The subject Styptin, Hemogin-L, Hemodettes, and GingiGEL impregnated Aluminum Chloride Retraction Cords are substantially equivalent to the predicate devices (**Table 5.2**) cleared by the FDA for commercial distribution in the United States.

The aluminum chloride impregnated retraction material is placed directly into the sulcus with a dental instrument according to the dental clinician's preference. The aluminum chloride impregnated retraction cord is left in place less than 5 minutes for the proposed Styptin, Hemogin-L, GingiGEL, and Hemodettes. After treatment, the retraction cord/pellet is removed, and the treated area is rinsed with water with simultaneous aspiration. The area is gently air dried to obtain a dry retracted sulcus to continue additional dental restorative treatment.

All of the proposed and predicate devices are retraction materials that are placed into the sulcus to exert a gentle force onto the gingival tissue to physically displace and retract the gingival tissue away from the tooth. This mechanical mode of action directly results in temporarily exposing the sub-gingival margin to aid in taking impressions or other dental restorative treatments.

Astringent/Hemostatic Agent: Aluminum Chloride:

The proposed and predicate devices incorporate an astringent/ hemostatic agent containing aqueous aluminum chloride solution or gel. . Simply stated, aluminum chloride temporarily constricts blood vessels and extracts fluid from tissues. Aluminum chloride has been used for many years in this manner to help maintain the visual field of the exposed sub-gingival margins due to the physical displacement by the retraction cord. This action results in clear dental impressions and operative dental procedures requiring a well-defined dental margin and hemostasis and fluid control.

Configuration/Application Method Summary:

The proposed devices combine a few variations in application method due to the variations in configuration.

- GingiGEL is an aluminum chloride impregnated, knit/twisted/ braided, cotton/ synthetic, retraction cords. These have been pre-impregnated prior to final packaging.
- Styptin and Hemogin-L are examples of aqueous aluminum chloride solutions or gels used in conjunction with a non-impregnated cotton cord.

- Hemodettes aqueous aluminum chloride solutions or gels used in conjunction with a non-impregnated cotton cord alterative, i.e. cotton pellets, coil, or caps.

Performance Testing

Non-Clinical Performance Data

Non-clinical performance data included aluminum chloride content assessment, shelf life assessment, visual inspection, material composition analysis, cutting test, water contact test, and biocompatibility assessment incorporating risk-to-benefit ratio analysis. The performance testing performed on Styptin, Hemogin-L, Hemodettes, and GingiGEL impregnated Aluminum Chloride Retraction Cord product line was tested and validated to the greatest challenge ("worst-case") within the Kerr Corporation portfolio of retraction cord products.

The subject device, Styptin, Hemogin-L, Hemodettes, and GingiGEL impregnated Aluminum Chloride Retraction Cord product line, directly contacts the patient for either less than 5 minutes.

The data from these tests substantiate that the proposed Styptin, Hemogin-L, Hemodettes, and GingiGEL Aluminum Chloride Impregnated Retraction Cords are substantially equivalent to the predicate devices,

Testing was conducting in accordance with the following standards:

- ISO 10993-1: 2009 (Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process)
- ISO 10993-5: 2009 (Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity)
- ISO 7405: 2008 (Dentistry - Evaluation of Biocompatibility of Medical Devices Used in Dentistry)

Table 5.4 Device Comparison Table Demonstrating Substantial Equivalence

Element	Proposed Devices *Styptin, Hemogin L, Hemodettes, and GingiGel*	Primary Predicate *GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord*	Reference Predicate *Expa-syl*	Reference Predicate *ViscoStat Clear*
510(k)	K162948	K162536	K050180	K123215
Trade/ Proprietary Name	*Styptin, Hemogin-L, Hemodettes,* and *GingiGEL* Aluminum Chloride impregnated Retraction Cords	*GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord*	*Expa-syl*	*ViscoStat Clear* (Manufacturer recommends using in conjunction with non-impregnated retraction cord.)
Common Name	Retraction Material	Retraction Material	Retraction Material	Retraction Material
Product Code	MVL	MVL	MVL	MVL
Device Class	Unclassified	Unclassified	Unclassified	Unclassified
510(k) Sponsor	Sybron Dental Specialties	Sybron Dental Specialties	Sybron Dental Specialties	Ultradent Products Inc. / OraTech LLC
Intended Use	Retraction Cords are for the temporary retraction of the gingival margins and hemostasis procedures.	Same	Same	Same
Indications for Use	Aluminum Chloride impregnated retraction material are for the	GingiKnit+, GingiBraid+, GingiBraid+ Shortcut,	Expa-syl is a paste containing aluminum chloride which is	*ViscoStat Clear* is intended for sulcus retraction prior to

Element	Proposed Devices *Styptin, Hemogin L, Hemodettes, and GingiGel*	Primary Predicate *GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord*	Reference Predicate *Expa-syl*	Reference Predicate *ViscoStat Clear*
	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.	and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cords 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.	intended to be used 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	impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the *Dento-Infusor*. The gel facilitates the insertion of the cord into the sulcus.
Target Users	Licensed dental professionals	Licensed dental professionals	Licensed dental professionals	Licensed dental professionals
Primary Mode of Action	Mechanical Displacement of gingival tissues for a short period prior to taking an impression	Same	Same	Same

Element	Proposed Devices *Styptin, Hemogin L, Hemodettes, and GingiGel*	Primary Predicate *GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord*	Reference Predicate *Expa-syl*	Reference Predicate *ViscoStat Clear*
	or other restorative procedures.			
Physical Configuration	Aluminum Chloride gel coated braid, Aqueous Aluminum Chloride solution, Cotton pellets saturated in buffered Aluminum Chloride gel	Aluminum Potassium Sulfate Impregnated Retraction Cord available as Knitted, Braided, Braided with ShortCut, and PreCut Single Unit Dose	Paste	Aqueous gel
Astringent/ Hemostatic Agent	Aluminum Chloride	Aluminum Potassium Sulfate	Aluminum Chloride	Aluminum Chloride
$AlCl_3$ Content *(weight/ volume %)*	1. *GingiGEL:* 20% $AlCl_3$ 2. *Styptin:* 20% $AlCl_3$ 3. *Hemogin-L:* 25% $AlCl_3$ 4. *Hemodettes*: 20% $AlCl_3$	None	15% $AlCl_3$	25% $AlCl_3$

Element	Proposed Devices *Styptin, Hemogin L, Hemodettes, and GingiGel*	Primary Predicate *GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord*	Reference Predicate *Expa-syl*	Reference Predicate *ViscoStat Clear*
Contact Time	1. *GingiGEL, Styptin, Hemogin-L, Hemodettes:* < 5 minutes	< 5 minutes	1-2 minutes	1-3 minutes
Shelf Life	1. *GingiGEL:* 36 months 2. *Styptin:* 36 months 3. *Hemogin-L:* 36 months 4. *Hemodettes*: 24 months	36 months	24 months	42 months
Material Compatibility	Biocompatibility meets requirements per ISO 10993	Biocompatibility meets requirements per ISO 10993	Biocompatibility meets requirements per ISO 10993	Biocompatibility meets requirements per ISO 10993
Primary Container	1. *GingiGEL:* Glass vial with snap-top cap 2. *Styptin: Liquid:* • 15mL – plastic squeeze bottle • 30mL – amber glass bottle	Glass vial with snap-top cap and specialized ShortCut system	Capsules	Plastic pre-filled, refillable, and IndiSpense refill syringes

Element	Proposed Devices *Styptin, Hemogin L, Hemodettes, and GingiGel*	Primary Predicate *GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord*	Reference Predicate *Expa-syl*	Reference Predicate *ViscoStat Clear*
	3. *Hemogin-L: Liquid:* • Amber glass bottles with eye dropper lid 4. *Hemodettes*: • Plastic unit dose cups with unique "finger ring" Cord in polybag			

Clinical Performance Data

Clinical performance testing has not been performed for the proposed device.

H. Conclusion as to Substantial Equivalence:

Styptin, Hemogin L, Hemodettes, and GingiGel Aluminum Chloride impregnated retraction material is substantially equivalent to the primary predicate GingiKnit+, GingiBraid+, GingiBraid+ Shortcut, and UniBraid+ impregnated Aluminum Potassium Sulfate Retraction Cord (K162536). Both the subject device and the predicate device have the same intended use, indications for use, target users, primary mode of action, material compatibility, and primary packaging. The proposed devices and the primary predicate both meet their intended use through physical and mechanical means to displace or retract gingival tissue temporarily for impression taking or other restorative procedures. The subject device and the primary predicate have different hemostatic agents and are available in different configurations. configurations. The reference predicate Expa-syl (K050180) was selected as it has a similar design, the same intended use and hemostatic agent / astringest as the Styptin, Hemogin L, Hemodettes, and GingiGel proposed devices. Expa-syl has a slightly lower $AlCl_3$ content of 15% whereas the proposed subject devices contain a slightly higher amount of either 20% or 25%. Any noted differences in technological characteristics between the proposed and predicate devices do not raise new questions of substantial equivalence. Styptin, Hemogin-L, Hemodettes, and GingiGEL Aluminum Chloride impregnated Retraction Material are substantially equivalent to the legally marketed predicate device Gingiknit+, Gingibraid+, Gingibraid+ Shortcut, and Unibraid+ Impregnated Aluminum Potassium Sulfate Retraction Cord (K162536), based on the design, performance, intended use, indications for use, and material compatibility.