March 14, 2022

Belport Company, Inc., Gingi-Pak
Mohammed Islam
Director of R&D
4825 Calle Alto
Camarillo, California 93012

Re: K211420
Trade/Device Name: Stasis Gel
Regulatory Class: Unclassified
Product Code: MVL
Dated: June 29, 2021
Received: July 23, 2021

Dear Mohammed Islam:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211420

Device Name
STASIS Gel

Indications for Use *(Describe)*
STASIS Gel is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord. STASIS Gel facilitates the insertion of the cord into the sulcus.

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 - K211420

I. SUBMITTER	
Name:	Gingi-Pak, a Division of Belport Co.
Address:	4825 Calle Alto Camarillo, CA 93012
Contact Person:	Summeya Islam
Email:	Su.islam@Gingi-Pak.com
Tel:	(805)484-1051
Date Prepared:	01/12/2021
II. Device	
Device Trade Name:	Stasis Gel
Common and Classification Names (s):	Cord, Retraction
Device Classification:	Unclassified
Product Code:	MVL
III. Predicate Device(s)	
Predicate Device Trade Name:	Vista FS
510 (k) Number:	K190220
Submitter:	Inter-Med/ Vista Dental Products
Device Classification:	Unclassified
Product Code:	MVL
Reference Device Trade Name:	Vista FS Liquid
510 (k) Number:	K190220
Submitter:	Inter-Med/ Vista Dental Products
Device Classification:	Unclassified
Product Code:	MVL

IV. Device Description			
Device Identification:	15.5% Ferric Sulfate in a water-based, viscous gel		
Device Characteristic:	Stasis Gel is supplied in a 30 ml or 1.2 ml plastic syringe. The 30 ml syringe is used for bulk storage and 1.2 ml plastic syringe is used for delivery the gel to the sulcus.		
Environment of Use:	Healthcare facility/ Dental office		
Summary (Description) of Device:	Stasis Gel is a 15.5% Ferric Sulfate in a water-based, viscous gel that facilitates sulcus retraction. When applied to the sulcus, the product provides physical displacement of the gingival tissue from the tooth, which in turn, provides a physical barrier to prevent gingival bleeding and oozing from following procedures.		
Material of Use:	Ferric Sulfate in a water-based gel		
V. Indications for Use			
	Stasis Gel is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord. Stasis Gel facilitates the insertion of the cord into the sulcus.		
VI. Comparison of Technological Characteristics with the Predicate Device			
	Predicate Device: **Vista FS** Oral Cavity	**Reference Device:** **Vista FS Liquid** Oral Cavity	**Subject Device:** **Stasis Gel** Oral Cavity
510(k) Number	K190220	K190220	K211420
Common Name	Cord, Retraction	Cord, Retraction	Cord, Retraction
Device Classification	Unclassified	Unclassified	Unclassified
Product Code	MVL	MVL	MVL
Indication for Use	Vista FS is intended for sulcus retraction	Vista FS Liquid is intended for sulcus retraction	Stasis Gel is intended for sulcus retraction

	prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord. Vista FS facilitates the insertion of the cord into the sulcus.	prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord. This device facilitate the insertion of the cord into the sulcus.	prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord. Stasis Gel facilitates the insertion of the cord into the sulcus.
Environment of Use	Healthcare offices / Dental offices	Healthcare offices / Dental offices	Healthcare offices / Dental offices
Target Population	Health care professionals	Health care professionals	Health care professionals
Prescription/ OTC	Prescription	Prescription	Prescription
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity
Chemical Characteristics	20% Ferric Sulfate	15.5% Ferric Sulfate	15.5% Ferric Sulfate
Mechanism of Action	Placement of the viscous gel results in physical displacement of gingival tissue from the tooth. Material also facilitates insertion of the cord into the sulcus.	Placement of the viscous gel results in physical displacement of gingival tissue from the tooth. Material also facilitates insertion of the cord into the sulcus.	Placement of the viscous gel results in physical displacement of gingival tissue from the tooth. Material also facilitates insertion of the cord into the sulcus.
Viscosity	Unknown	Unknown	$\geq$ 55,000 cps
pH	Unknown	1-3	1-3

Packaging Configuration	1.2mL pre-filled syringe with applicator tips; 30mL syringe with empty 1.2mL syringes and applicator tips.	1.2mL pre-filled syringe with applicator tips; 30mL syringe with empty 1.2mL syringes and applicator tips	1.2mL pre-filled syringe with applicator tips; 30mL syringe with empty 1.2mL syringes and applicator tips.
Sterility	Non-sterile	Non-sterile	Non-sterile
Shelf-Life	18 months	18 months	24 months
Recommended Contact Time	1-3 minutes	1-3 minutes	1-3 minutes
Biocompatibility	Cytotoxicity	Cytotoxicity	Cytotoxicity Skin Sensitization Skin Irritation
VII. Summary of Testing (Non-Clinical)			
Biocompatibility	Biocompatibility testing are performed according to ISO 10993-1. Device demonstrated low cytotoxicity, skin sensitization and skin irritation.		
Bench Testing	Stasis Gel has been tested for Ferric Sulfate content and is found to be similar to predicate device.		
Sterility and Shelf-Life Testing	Stasis Gel is not supplied as sterile. Based on accelerated testing, a shelf life of two years is supported for Stasis Gel. Real time aging is being performed on Stasis Gel to support shelf life during typical storage conditions.		
VIII. Conclusion			
Stasis Gel is determined to be substantially equivalent to Vista FS (K190220). The subject medical device has a nearly identical intended use and chemical characteristics and delivery system as the predicate device. Any differences between the subject medical device and predicate medical device do not significantly alter the product's use and do not result in unacceptable or unnecessary risks to the patients or users. Therefore, we conclude that Stasis Gel is substantially equivalent to the predicate device, Vista FS.			