June 10, 2019

Inter-Med / Vista Dental Products
Alex Johnson
Sr. Product Development Engineer
2200 South St. Ste. A
Racine, Wisconsin 53404

Re: K190220
Trade/Device Name: Vista FS, Vista FS Liquid
Regulatory Class: Unclassified
Product Code: MVL
Dated: March 7, 2019
Received: March 12, 2019

Dear Alex Johnson:

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,

Srinivas Nandkumar, PhD
Acting Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190220

Device Name
Vista FS and Vista FS Liquid

Indications for Use *(Describe)*
Vista FS and Vista FS Liquid are 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 and Vista FS Liquid facilitate 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
for
Vista FS and Vista FS Liquid

1. Applicant

Submitter's Name: Alex Johnson, MSc
John Baeten, MSc

Date Summary Prepared: March 7, 2019

Address: Inter-Med / Vista Dental Products
2200 South St. Ste A
Racine, WI, USA 53404

Contact Person: Alex Johnson, MSc

Phone: (262) 631-5306

Email: ajohnson@vista-dental.com

Fax: (262) 636-9760

2. Device Name

Proprietary Name: Vista FS and Vista FS Liquid
Common Name: Cord, Retraction
Product Code: MVL
Device Class: Unclassified

3. Primary Predicate Device

ViscoStat Clear (K123215) by Ultradent Products
- Common Name: Cord, Retraction
- Product Code: MVL
- Device Class: Unclassified

Additional Predicate Device

Astringedent Clear (K152064) by Ultradent Products
- Common Name: Cord, Retraction
- Product Code: MVL
- Device Class: Unclassified

Reference Devices

ViscoStat (pre-amendment device) by Ultradent Products
- Common Name: Cord, Retraction
- Product Code: MVL
- Device Class: Unclassified

Astringedent (pre-amendment device) by Ultradent Products
- Common Name: Cord, Retraction
- Product Code: MVL
- Device Class: Unclassified

4. Device Description

Vista FS and Vista FS Liquid are medical devices used to facilitate sulcus retraction prior to taking a dental impressions of a tooth. This entails placement of the devices into the sulcus which provides physical displacement of the gingival tissue from the tooth. If using a gingival retraction cord, the subject devices facilitate the insertion of the cord into the sulcus while also facilitating the creating of a physical barrier to prevent gingival bleeding and oozing from affecting restorative and tissue management procedures.

This is the only 510(k) for these medical devices, no prior 510(k)s have been submitted.

5. Intended Use / Indication for Use

Vista FS and Vista FS Liquid are 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. These devices facilitate the insertion of the cord into the sulcus.

6. Technological Characteristics and Substantial Equivalence

	Subject Device: Vista FS	**Subject Device: Vista FS Liquid**	**Primary Predicate Device: ViscoStat Clear**	**Predicate Device: Astringedent Clear**	**Reference Device: ViscoStat**	**Reference Device: Astringedent**
Manufacturer	Inter-Med / Vista Dental Products	Inter-Med / Vista Dental Products	Ultradent Products	Ultradent Products	Ultradent Products	Ultradent Products
510(k) Number	K190220	K190220	K123215	K152064	Not applicable; pre-amendment device	Not applicable; pre-amendment device
Common Name	Cord, Retraction	Cord, Retraction	Cord, Retraction	Cord, Retraction	Cord, Retraction	Cord, Retraction
Device Classification	Unclassified	Unclassified	Unclassified	Unclassified	Not applicable	Not applicable
Product Code	MVL	MVL	MVL	MVL	Not applicable	Not applicable
Indication for Use	Vista FS and Vista FS Liquid are 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. These devices facilitate the insertion of the cord into the sulcus.	Vista FS and Vista FS Liquid are 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. These devices facilitate the insertion of the cord into the sulcus.	ViscoStat Clear 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 and/or the Dento Infusor. These gels facilitate the insertion of the cord into the sulcus.	Astringedent Clear 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 and/or the Dento Infusor. The solution facilitate the insertion of the cord into the sulcus.	Pre-amendment device; FDA Form 3881 does not exist for this product.*	Pre-amendment device; FDA Form 3881 does not exist for this product.*

	Subject Device: Vista FS	Subject Device: Vista FS Liquid	Primary Predicate Device: ViscoStat Clear	Predicate Device: Astringedent Clear	Reference Device: ViscoStat	Reference Device: Astringedent
Where used	Dental offices and health care offices	Dental offices and health care offices	Dental offices and health care offices	Dental offices and health care offices	Dental offices and health care offices	Dental offices and health care offices
Target population	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals
Anatomical site	Oral cavity	Oral cavity	Oral cavity	Oral cavity	Oral cavity	Oral cavity
Trivalent Cationic Salt	20% ferric sulfate in aqueous-based gel	15.5% ferric sulfate in aqueous liquid	25% aluminum chloride in aqueous-based gel	25% aluminum chloride in aqueous liquid	20% ferric sulfate in aqueous-based gel	15.5% ferric sulfate in aqueous liquid
Viscosity	Viscous gel	Liquid	Viscous gel	Liquid	Viscous gel	Liquid
Mechanism of Action	Placement of the material results in physical displacement of gingival tissue from the tooth. Material also facilitates insertion of the cord into the sulcus.	Placement of the material results in physical displacement of gingival tissue from the tooth. Material also facilitates insertion of the cord into the sulcus.	Placement of the material results in physical displacement of gingival tissue from the tooth. Material also facilitates insertion of the cord into the sulcus.	Placement of the material results in physical displacement of gingival tissue from the tooth. Material also facilitates insertion of the cord into the sulcus.	Placement of the material results in physical displacement of gingival tissue from the tooth. Material also facilitates insertion of the cord into the sulcus.	Placement of the material results in physical displacement of gingival tissue from the tooth. Material also facilitates insertion of the cord into the sulcus.
Packaging Configuration	1.2mL pre-filled syringe with applicator tips	30mL bottle	1.2mL pre-filled syringe with applicator tips	30mL bottle	1.2mL pre-filled syringe with applicator tips	30mL bottle
	30mL syringe with empty 1.2mL syringes and applicator tips.	30mL syringe	30mL syringe with empty 1.2mL syringes and applicator tips.	30mL syringe	30mL syringe with empty 1.2mL syringes and applicator tips.	30mL syringe
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile

	Subject Device: Vista FS	Subject Device: Vista FS Liquid	Primary Predicate Device: ViscoStat Clear	Predicate Device: Astringedent Clear	Reference Device: ViscoStat	Reference Device: Astringedent
Shelf-Life	18 months	18 months	42 months	Unknown	48 months	48 months
Biocompatibility Testing Performed	Cytotoxicity	Cytotoxicity	Cytotoxicity	None	Unknown	Unknown
Recommended Contact Time	1-3 minutes	1-3 minutes	1-3 minutes	1-3 minutes	1-3 minutes	1-3 minutes
Prescription / OTC	Prescription	Prescription	Prescription	Prescription	Prescription	Prescription

*An FDA Form 3881 does not exist for these reference devices because these devices are pre-amendment medical devices. As such, the indications for use for these devices is not explicitly known by Inter-Med / Vista Dental Products. Regardless, these reference devices are only incorporated for reference only and represent pre-amendment devices.

Similarities between the subject devices (Vista FS and Vista FS Liquid) and predicate devices (ViscoStat Clear and Astringedent Clear)

- Vista FS and Vista FS Liquid have nearly identical indications for use as the predicate devices; the only differences are the medical device names and removal of the "Dento Infusor" as this is not a Vista Dental product.
- Vista FS and Vista FS Liquid are classified under product code MVL and share the identical common name "Cord, Retraction" as the predicate devices.
- Vista FS and Vista FS Liquid have the same recommended contact time (1-3 minutes) as the predicates, ViscoStat Clear and Astringedent Clear.
- Vista FS and Vista FS Liquid are identical to the predicate devices as all products are aqueous materials (i.e gels or liquids) which aid in the physical retraction of gingival tissue, and can be used with retraction cord.
- Vista FS and Vista FS Liquid are used in the same target population and anatomical site as the predicate devices.
- Identical to the predicate device, Vista FS and Vista FS Liquid are for prescription use only by healthcare professionals.
- Vista FS is offered in the same configurations as the predicate device, ViscoStat Clear (i.e. prefilled syringes with applicator tips, or bulk syringes with unfilled smaller syringes and applicator tips).
- Vista FS Liquid is offered in the same configurations as the predicate device, Astringedent (i.e. a bulk syringe, or a bottle).
- Vista FS and Vista FS Liquid have identical technological characteristics as the predicate devices, ViscoStat Clear and Astringedent Clear.
    - All medical devices contain an aqueous solution of a trivalent cationic salt. ViscoStat Clear and Astringedent Clear contain aluminum chloride, and Vista FS and Vista FS Liquid contain ferric sulfate
    - All medical devices have an identical pH.
    - All medical devices exhibit identical results within cytotoxicity testing.
    - All medical devices exhibit identical results within microbiological testing.
- Identical to the predicate devices, Vista FS and Vista FS Liquid represent a viscous gel device and a liquid device compared to ViscoStat Clear and Astringedent Clear, respectively, for nearly identical indications for use.

Vista FS and Vista FS Liquid share similar intended uses, technical characteristics, and method of application to the predicate devices (ViscoStat Clear and Astringedent Clear). Therefore, Vista FS and Vista FS Liquid are substantially equivalent to the predicate devices and pose no additional safety risks.

This is the only 510(k) for these medical devices, no prior 510(k)s have been submitted.

Differences between the subject devices (Vista FS and Vista FS Liquid) and predicate device (ViscoStat Clear and Astringedent Clear)

- Vista FS and Vista FS Liquid contain ferric sulfate, whereas the predicate devices, ViscoStat Clear and Astringedent Clear, contain aluminum chloride.
    - However, this difference does not raise any safety or efficacy concerns as ferric sulfate and aluminum chloride are both trivalent cationic salts.
    - Furthermore, ViscoStat and Astringedent represent commercialized medical devices that contain ferric sulfate at identical concentrations to the subject devices, for use in the same dental procedures as the subject device, and for similar indications for use as the subject devices. ViscoStat and Astringedent have been on the market for over 40 years and are well-known safe and biocompatible retraction cord medical devices.
    - Therefore, this difference does not raise any additional safety or efficacy concerns and the subject devices remain substantially equivalent.
- Vista FS and Vista FS Liquid have a shelf-life of 18 months, whereas the predicate device (ViscoStat Clear) has a shelf-life of 42 months.
    - This difference does not raise any safety or efficacy risks as the subject devices have shown safety and efficacy commensurate with the listed shelf-life and have labeling which adequately communicates shelf-life to the user.
    - Ongoing accelerated and real-time shelf-life testing will determine the most appropriate shelf-life constraints for Vista FS and Vista FS Liquid. The labeling and user manual for Vista FS and Vista FS Liquid will be updated accordingly to communicate the most appropriate shelf-life constraints to users.
    - Therefore, the subject devices remain substantially equivalent to the predicate devices.

Applicable Standards

- ISO 10993-1:2009 Biological Evaluation of Medical Devices Part 1 – Evaluation and Testing
- ISO 14971:2007 – Application of Risk Management to Medical Devices
- ISO 14971:2012 – Application of Risk Management to Medical Devices

7. Non-Clinical Performance Testing and Compliance

The following non-clinical tests were conducted to evaluate the functionality, performance, safety, and substantial equivalence of Vista FS and Vista FS Liquid to ViscoStat Clear and Astringedent Clear:

- DHF10011-TR001 – Analytical Testing
    - Testing verified manufacturing of Vista FS and Vista FS Liquid. Results from testing are commensurate with the predicate devices and reference devices, supporting substantial equivalence of the subject devices to existing commercialized devices.

- DHF10011-TR002 – Cytotoxicity Testing
  - Vista FS and Vista FS Liquid do not exhibit any differences in cytotoxicity when compared to the currently marketed and sold product for the same intended use (i.e. the predicate device - ViscoStat Clear). All products in this testing were found to have the same result at all dilutions evaluated.
  - This testing confirms that the subject devices are substantially equivalent to the predicate devices in safety for their intended use. Combined with DHF10011-BS and DHF10011-CER, Inter-Med concludes that no further biocompatibility testing or clinical evaluation is needed before release of this product to the market.
- DHF10011-TR003 – Shelf-Life Testing
  - This test report represents an interim analysis of the accelerated shelf-life testing performed to-date. All test data for the 18 month time point were significantly within test acceptance criteria, so accelerated shelf-life testing will continue through 36 months of accelerated testing to provide a suggested shelf-life for Vista FS and Vista FS Liquid.
  - An additional test report will be written to summarize the completed accelerated shelf-life testing. Real-time shelf-life testing will be run in parallel to confirm actual shelf-life parameters for these medical devices.
- DHF10011-TR004 – Microbiological Testing
  - Contamination risks from manufacturing are mitigated as Vista FS and Vista FS Liquid exhibit bactericidal properties. Furthermore, these results help to support shelf stability and multiple use of non-patient contacting materials, such as the syringes, as any introduced microbes will not remain viable within the medical device.
  - It should be noted that Vista Dental Products is not claiming any "bactericidal" effect of the subject medical devices. This testing was performed solely to evaluate risk of contamination during manufacturing.
- DHF10011-TR005 – Transit Testing
  - This test confirms that the packaging configurations are sufficient and withstand simulated transit conditions. Moreover, the products performed satisfactory post-transit, which confirms that transit did not have a negative effect on the products themselves.

8. Clinical Performance Testing and Compliance

Clinical performance is not deemed necessary.

9. Conclusion

Vista FS and Vista FS Liquid are to be marketed by Inter-Med / Vista Dental Products, 2200 South St. Ste. A., Racine, WI 53404, and are substantially equivalent to ViscoStat Clear (K123215) and Astringedent Clear (K152064). The subject medical devices have a nearly identical intended use and technological characteristics, and all devices are substantially equivalent in safety and effectiveness when used for the described indications.

Any differences between the subject medical devices and predicate medical devices are substantiated from reference devices (ViscoStat and Astringedent), which represent commercially available medical devices of identical technical characteristics.