March 4, 2020

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

Re: K193389
Trade/Device Name: Vista Clear
Regulatory Class: Unclassified
Product Code: MVL
Dated: December 5, 2019
Received: December 6, 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,

for Srinivas “Nandu” Nandkumar, Ph.D.
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)*
K193389

Device Name
Vista Clear

Indications for Use *(Describe)*
Vista 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. Vista Clear 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.

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

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510(k) Summary
for
Vista Clear

1. Applicant

Submitter's Name: Alex Johnson, MSc **Date Summary Prepared:** December 5, 2019

Address: Inter-Med / Vista Dental Products **Contact Person:** Alex Johnson, MSc
2200 South St. Ste A
Racine, WI, USA 53404

Phone: (262) 631-5306 **Email**: ajohnson@vista-dental.com

Fax: (262) 636-9760

2. Device Name

Proprietary Name: Vista Clear
Common Name: Cord, Retraction
Product Code: MVL
Device Class: Unclassified

3. Predicate Device

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

4. Device Description

Vista Clear is used to facilitate sulcus retraction prior to taking a dental impression of a tooth. This entails placement of the device into the sulcus which provides physical displacement of the gingival tissue from the tooth. If using a gingival retraction cord, the subject device facilitates the insertion of the cord into the sulcus while also creating 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 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. Vista Clear facilitates the insertion of the cord into the sulcus.

6. Technological Characteristics and Substantial Equivalence

	Predicate Device: ViscoStat® Clear (Ultradent Products)	**Vista Clear (Inter-Med / Vista Dental Products)**
510(k) Number	K123215	Pending (subject device for this 510(k) submission)
Common Name	Cord, Retraction	Cord, Retraction
Device Classification	Unclassified	Unclassified
Product Code	MVL	MVL
Indication for Use	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.	Vista 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. Vista Clear facilitates the insertion of the cord into the sulcus.
Where used	Dental offices and health care offices	Dental offices and health care offices
Target population	Health care professionals	Health care professionals
Anatomical site	Oral cavity	Oral cavity
Chemical characteristics	25% Aluminum chloride	26.6% Aluminum chloride hexahydrate
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.
Viscosity	Viscous gel	Viscous gel
Packaging Configuration	1.2mL pre-filled syringe with applicator tips	1.2mL pre-filled syringe with applicator tips
	30mL syringe with empty 1.2mL syringes and applicator tips.	30mL syringe with empty 1.2mL syringes and applicator tips.

	Predicate Device: ViscoStat® Clear (Ultradent Products)	Vista Clear (Inter-Med / Vista Dental Products)
Sterility	Non-sterile	Non-sterile
Shelf-Life	42 months	24 months
Biocompatibility Testing Performed	Cytotoxicity	Cytotoxicity
Recommended Contact Time	1-3 minutes	1-3 minutes
Prescription / OTC	Prescription	Prescription

Similarities between the subject device (Vista Clear) and predicate device (ViscoStat Clear)

- Vista Clear has nearly identical indications for use as the predicate device, ViscoStat Clear.
- Vista Clear is classified under product code MVL and shares the identical common name "Cord, Retraction" as the predicate device.
- Vista Clear has the same recommended contact time (1-3 minutes) as the predicate, ViscoStat Clear.
- Vista Clear is identical to the predicate device as both products are aqueous gels which aid in the physical retraction of gingival tissue.
- Vista Clear is used in the same target population and anatomical site as the predicate device.
- Identical to the predicate device, Vista Clear is for prescription use only by healthcare professionals.
- Vista Clear is offered in the same configurations as the predicate device (i.e. prefilled syringes with applicator tips, or bulk syringes with unfilled smaller syringes and applicator tips).
- Vista Clear has identical technological characteristics to the predicate device:
    - Both medical devices contain an aqueous solution of a trivalent cationic salt (aluminum chlorite).
    - Both medical devices have an identical pH.
    - Both medical devices exhibited identical results within cytotoxicity and microbiological testing.

Vista Clear shares similar intended uses, technical characteristics, and methods of application to the predicate device (ViscoStat Clear). Therefore, Vista Clear is substantially equivalent to the predicate device.

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

Differences between the subject device (Vista Clear) and predicate device (ViscoStat Clear)

- Vista Clear contains 26.6% aluminum chloride hexahydrate whereas the predicate device contains 25% aluminum chloride.
    - However, this different does not raise any safety or efficacy concerns as they are analogous materials (i.e. aluminum chloride). In fact, Vista Clear is analogously effective as the predicate device yet includes a lower amount of aluminum chloride.
    - Therefore, this difference does not raise any additional safety or efficacy concerns and the subject device remains substantially equivalent to the predicate device.
- Vista Clear has a shelf-life of 24 months, whereas the predicate device has a shelf-life of 42 months.
    - This difference does not raise any safety or efficacy risks as the subject device has shown safety and efficacy commensurate with the listed shelf-life and the product has labeling which adequately communicates shelf-life to the user.

Applicable Standards

- ISO 10993-1 – Biological Evaluation of Medical Devices Part 1 – Evaluation and Testing
- ISO 14971 – Application of Risk Management to Medical Devices
- ISO 594-1 – Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
- ISO 594-2 – Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings

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 Clear to ViscoStat Clear:

- Analytical Testing
    - Testing verified manufacturing of Vista Clear. Results from testing are commensurate with the predicate device, supporting substantial equivalence of the subject device to an existing commercialized device.
- Cytotoxicity Testing
    - Vista Clear exhibited the same cytotoxicity result as the predicate device (ViscoStat Clear) sold for the same intended use.
    - This testing confirms that the subject device is substantially equivalent to the predicate device. Combined with DHF-10043-BS and DHF-10043-CER, Inter-Med concludes that no further biocompatibility testing or clinical evaluation is needed before release of this product to the market.
- Shelf-Life Testing

- Based on accelerated testing, a shelf life of two years is supported for Vista Clear. Real time aging is being performed on Vista Clear to support shelf life during typical storage conditions.

- Microbiological Testing
  - Contamination risks from manufacturing are mitigated as Vista Clear exhibits 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 device. This testing was performed solely to evaluate risk of contamination during manufacturing.
- 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 Clear is to be marketed by Inter-Med / Vista Dental Products, 2200 South St. Ste. A., Racine, WI 53404, and is substantially equivalent to ViscoStat Clear (K123215). The subject medical device has a nearly identical intended use and technological characteristics 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, Inter-Med concludes that Vista Clear is substantially equivalent to the predicate device, ViscoStat Clear.