March 11, 2020

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

Re: K193447
Trade/Device Name: Vista Dyes
Regulation Number: 21 CFR 872.1740
Regulation Name: Caries Detection Device
Regulatory Class: Class II
Product Code: LFC
Dated: December 10, 2019
Received: December 13, 2019

Dear Mr. 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)*
K193447

Device Name
Vista Dyes

Indications for Use *(Describe)*

A visual aid for the identification of carious dentin.

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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K193447

510(k) Summary
for
Vista Dyes

1. Applicant

Submitter's Name: Alex Johnson, MSc **Date Summary Prepared:** March 10, 2020

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. Devce Name

Proprietary Name: Vista Dyes
Common Name: Device, Caries Detection
Product Code: LFC
Device Class: Class II

3. Primary Predicate

Caries Finder (K955445) by Danville Engineering, Inc.

- Common Name: Device, Caries Detection
- Product Code: LFC
- Device Class: Class II

Reference Device:

Pulpdent Snoop (K964430) by Pulpdent Corp.

- Common Name: Device, Caries Detection
- Product Code: LFC
- Device Class: Class II

4. Device Description

Vista Dyes are colored agents that when applied to the suspected carious areas of the tooth stains the carious dentin. The method of operation and placement of Vista Dyes are similar to that of the primary predicate and reference device, Caries Finder (K955445) and Pulpdent Snoop (K964430), respectively. A drop of the dye is applied to the carious dentine, rinsed with water and air dispersed. The stained carious tissue is then removed with a low speed rotary bur. The process may be repeated until there are no more stainable tissues in the carious cavity.

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

5. Intended Use / Indications for Use

A visual aid for the identification of infected carious dentin.

6. Technological Characteristics and Substantial Equivalence

	Subject Device: Vista Dyes	**Primary Predicate: Caries Finder**	**Reference Device: Pulpdent Snoop**
Manufacturer	Inter-Med / Vista Dental Products	Danville Engineering, Inc.	Pulpdent Corp.
510(k) Number	Pending (subject device for this 510(k) submission)	K955445	K964430
Common Name	Device, Caries Detection	Device, Caries Detection	Device, Caries Detection
Device Classification	Class II	Class II	Class II
Product Code	LFC	LFC	LFC
Indications for Use	A visual aid for the identification of infected carious dentin.	A visual aid for the identification of infected carious dentin.	A visual aid for the identification of infected carious dentin.
Where used	Dental offices	Dental offices	Dental offices
Target population	Patients undergoing dental procedures	Patients undergoing dental procedures	Patients undergoing dental procedures
Anatomical site	Oral cavity	Oral cavity	Oral cavity
Physical Properties	Colored aqueous liquid	Colored aqueous liquid	Colored aqueous liquid
Chemical Properties	Red & Green Color: 99% propylene glycol 1% dye (red = acid red 52; green = FD&C green)	Red & Green Color: 99% propylene glycol 1% dye (red = acid red 52; green = FD&C green)	Not applicable (no red or green dye)

	Subject Device: Vista Dyes	Primary Predicate Device: Caries Finder	Reference Device: Pulpdent Snoop
	99% distilled water 1% methylene blue dye	Not applicable (no blue dye)	49.5% propylene glycol 49.5% distilled water 1% methylene blue dye
Mechanism of Action	Visible staining of carious dentin	Visible staining of carious dentin	Visible staining of carious dentin
Packaging Configuration	Prefilled dropper bottle Prefilled 1.2mL syringe	Prefilled dropper bottle	Prefilled dropper bottle
Sterility	Non-sterile	Non-sterile	Non-sterile
Active Ingredients	1% dye (red = acid red 52; green = FD&C green)	1% dye (red = acid red 52; green = FD&C green)	Not applicable (no red or green dye)
	1% methylene blue dye	Not applicable (no blue dye)	1% methylene blue dye
Shelf-Life	3 years	3 years	Unknown
Prescription / OTC	Prescription use only	Prescription use only	Prescription use only

Similarities between the subject device (Vista Dyes) and primary predicate (Caries Finder):

- Vista Dyes and Caries Finder have identical indications for use.
- Vista Dyes are classified under product code LFC and shares the identical common name "Device, Caries Detection" as the predicate device, Caries Finder.
- Vista Dyes are identical to the primary predicate as all products are liquid medical devices composed of propylene glycol and/or water and a colored dye.
- Vista Dyes are used in the same target population and anatomical site as the primary predicate.
- Identical to the primary predicate, Vista Dyes are for prescription use only by healthcare professionals.
- Vista Dyes is offered in the same configurations as the primary predicate (i.e. filled dropper bottles).
- Vista Dyes have identical shelf-life to the primary predicate (36 months).
- Vista Dyes have identical technological characteristics to the primary predicate:
    - All medical devices contain a colored dye in a liquid media.
    - The colored dye in Vista Dyes is identical to the colored dye found in the primary predicate and reference device.
    - The colored dye in Vista Dyes is incorporated at identical concentrations to that of the primary predicate and reference device.

Vista Dyes share identical intended uses, technical characteristics, and methods of application to the primary predicate (Caries Finder).

Differences between the subject device (Vista Dyes) and predicate device (Caries Finder)

- The blue-colored device of Vista Dyes is 1% dye in 99% water whereas the predicate device, Caries Finder, uses propylene glycol as the liquid media instead of water.
    - This difference does not raise concerns or risks as reference is made to the a previously 510(k) cleared reference device, Pulpdent Snoop (K964430), which is 1% dye in 99% water.
    - Therefore, the subject devices remain substantially equivalent to the predicate device, in light of the reference device.
- Vista Dyes are packaged in 10mL dropper bottles and 1.2mL prefilled syringes, whereas the predicate device is only packaged in 10mL dropper bottles.
    - This difference does not raise concerns or risks as the additional packaging configuration (i.e. 1.2mL prefilled syringe) is very common in the dental field for application of dental materials. Additionally, this packaging configuration helps to simplify the application of Vista Dyes, as material can be expressed directly from the syringe onto the tooth in a controlled fashion using an applicator tip.

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 and support the substantial equivalence of Vista Dyes:

- Shelf-Life Testing
    - Based on accelerated testing, a shelf life of three years is supported for Vista Dyes. Real time aging is being performed on Vista Dyes to support shelf life during typical storage conditions.

Additionally, given the long history of use of similar devices, and the fact the proposed device features identical constituents as the predicate and reference devices, the biocompatibility of Vista Dyes was confirmed via a literature review, LD50 analysis of product constituents, existing FDA data, and long-standing use of the predicate device in commerce without significant reportable events (MAUDE database).

8. Clinical Performance Testing and Compliance

Clinical performance is not deemed necessary to support the substantial equivalence of the proposed device.

9. Conclusion

Vista Dyes are to be marketed by Inter-Med / Vista Dental Products, 2200 South St. Ste. A., Racine, WI 53404, and is deemed to be substantially equivalent to primary predicate Caries Finder (K955445). The proposed device and its primary predicate have identical intended use and technological characteristics as the predicate device, and both devices are suitable for their described indications. Any differences between the subject device and primary predicate device do not significantly alter the product's use and do not result in unacceptable or unnecessary concerns for the patients or users. Further, any differences between the subject and predicate devices are substantiated from and addressed in the reference device (Pulpdent Snoop, K964430). Therefore, Inter-Med / Vista Dental Products concludes that Vista Dyes are substantially equivalent to the predicate device, Caries Finder.