October 23, 2020

Inter-Med/ Vista Dental Products
Katherine Barry
Product Development Engineer
2220 South Street Suite A
Racine, Wisconsin 53404

Re: K193357
Trade/Device Name: V-Mix
Regulatory Class: Unclassified
Product Code: KJJ
Dated: September 22, 2020
Received: September 23, 2020

Dear Katherine Barry:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K193357

Device Name
V-Mix

Indications for Use *(Describe)*
V-Mix is used for debridement, removing the smear layer, and cleansing the root canal system.

Type of Use *(Select one or both, as applicable)*

[X] 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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K193357

510(k) Summary
for
V-Mix

1. Applicant

Submitter's Name: Katherine Barry, MSc **Date Summary Prepared:** September 21, 2020

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

Contact Person: Katherine Barry, MSc

Phone: (262) 635-8956
Fax: (262) 636-9760

Email: kbarry@vista-dental.com

2. Device Name

Proprietary Name: V-Mix
Common Name: Cleanser, Root Canal
Product Code: KJJ
Device Class: Unclassified

3. Predicate Devices

Chlor-Xtra (K082470) by Inter-Med / Vista Dental Products
- Common Name: Cleanser, Root Canal
- Product Code: KJJ
- Device Class: Unclassified

Biopure MTAD Root Canal Cleanser (K053167) by Dentsply
- Common Name: Cleanser, Root Canal
- Product Code: KJJ
- Device Class: Unclassified

Vista Rinse Plus (K193409) by Inter-Med / Vista Dental Products
- Common Name: Cleanser, Root Canal
- Product Code: KJJ
- Device Class: Unclassified

4. Device Description

V-Mix is a two-part, dual-action root canal cleanser. V-Mix A is an aqueous solution that contains carboxylic acid chelating agents and surfactants. V-Mix B is an aqueous solution that contains sodium hypochlorite. Once the two solutions are mixed, the mixed solution cleanses and debrides the root canal system by removing the organic and inorganic debris during and after endodontic instrumentation.

5. Intended Use / Indication for Use

V-Mix is used for debridement, removing the smear layer, and cleansing the root canal system.

6. Technological Characteristics and Substantial Equivalence

Technological Characteristics

Most all the components found in V-Mix have been used in legally marketed devices or were found safe for dental use. We believe that the prior use of components in legally marketed devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of V-Mix for the indicated uses.

Substantial Equivalence

	Subject Device: V-Mix	**Primary Predicate Device: Chlor-XTRA™**	**Predicate Device: BioPure MTAD Root Canal Cleanser**	**Predicate Device: Vista Rinse Plus**
Manufacturer	Inter-Med / Vista Dental Products	Inter-Med / Vista Dental Products	DENTSPLY INTL	Inter-Med / Vista Dental Products
510(k) Number	K193357	K082470	K053167	K193409
Common Name	Cleanser, Root Canal	Cleanser, Root Canal	Cleanser, Root Canal	Cleanser, Root Canal
Device Classification	Unclassified	Unclassified	Unclassified	Unclassified
Product Code	KJJ	KJJ	KJJ	KJJ
Indication for Use	V-Mix is used for debridement, removing the smear layer, and cleansing the root canal system.	Chlor-XTRA™ is a solution used for debridement and the instrumentation of root canal.	BioPure MTAD is used to chemically clean the canal and disinfect the root canal system after endodontic instrumentation.	Vista Rinse Plus is an endodontic irrigating solution that cleanses the root canal system by removing the smear layer after endodontic instrumentation.
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
Target population	Patients undergoing endodontic therapy	Patients undergoing endodontic therapy	Patients undergoing endodontic therapy	Patients undergoing endodontic therapy
Anatomical site	Oral cavity	Oral cavity	Oral cavity	Oral cavity

	Subject Device: V-Mix	Primary Predicate Device: Chlor-XTRA™	Predicate Device: BioPure MTAD Root Canal Cleanser	Predicate Device: Vista Rinse Plus
Physical Properties	Clear, pale yellow, aqueous solution with a chlorine-like odor	Clear, pale yellow, aqueous solution with a chlorine-like odor	Clear, colorless, odorless liquid	Clear, colorless, odorless aqueous solution
Chemical Properties	Carboxylic acid chelating agents and sodium hypochlorite	Sodium hypochlorite solution	Carboxylic acid chelating agent	Carboxylic acid chelating agent
Mechanism of Action	The mechanical action of the solution moving in the root canal facilitates ease in the removal of debris and necrotic pulp tissue from the root canal.	Used for debridement and in the instrumentation of the root canal.	The mixed solution cleanses the root canal, removes the smear layer, and kills the bacteria in an instrumented root canal without harming the tooth structure or soft tissue.	The mechanical action of the solution moving in the root canal facilitates ease in the removal of debris and necrotic pulp tissue from the root canal.
Packaging Configuration	10mL pre-filled dual cartridge syringe with applicator tip	3mL and 12mL pre-filled syringe and 480mL bottle	Pre-filled 5mL syringe paired with a pre-filled 150mg bottle and a pre-filled 20mL syringe with a pre-filled 600mg bottle	120mL and 480mL bottles and 6mL syringe
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Active Ingredients	2-phophonobutane-1,2,4-Tricarboxylic acid (PBTC), Citric acid, and Sodium Hypochlorite (NaOCl)	Sodium Hypochlorite (NaOCl)	Citric acid and Doxycycline Hyclate	Ethylenediaminetetraacetic acid (EDTA) and Chlorhexidine digluconate (CHX)
Shelf-Life	18 months	24 months	Unknown	24 months
Prescription / OTC	Prescription	Prescription	Prescription	Prescription

Similarities between the subject device (V-Mix) and the predicate devices (Chlor-XTRA™, Biopure MTAD Root Canal Cleanser, and Vista Rinse Plus)

- V-Mix has similar indications for use as the predicate devices.
- V-Mix is classified under product code KJJ and shares the identical common name "Cleanser, Root Canal" as the predicate devices.
- Identical to the predicate devices, V-Mix is a non-sterile device.
- V-Mix and all the predicate devices contain surfactants.
- V-Mix and the primary predicate device, Chlor-XTRA™ (K082470), contain sodium hypochlorite as the active ingredient.
- V-Mix and the predicate device, Biopure MTAD Root Canal Cleanser (K053167), both contain citric acid, a carboxylic acid chelating agent.

- V-Mix and the predicate device, Vista Rinse Plus (K193409), both contain a carboxylic acid chelating agent.
- V-Mix and the predicate device, Biopure MTAD Root Canal Cleanser (K053167), are both two-part products, that when mixed, cleanse the root canal and remove smear layer in the instrumented root canal.
- V-Mix and Chlor-XTRA have identical physical properties, a clear, pale yellow, aqueous solution with a chlorine-like odor.
- V-Mix is identical to the predicate devices as all products are aqueous, endodontic irrigants.
- V-Mix is used in the same target population and anatomical site as the predicate devices (i.e. oral cavity).
- Identical to the predicate devices, V-Mix is for prescription use only by healthcare professionals.
- V-Mix is administered identically to the predicate devices. All irrigants are delivered via a syringe and endodontic irrigating needle tip.
- Identical to Chlor-XTRA, V-Mix is similar in biocompatibility for its intended use, as evident by the biocompatibility testing.

V-Mix shares similar intended uses, technical characteristics, and method of application to the predicate devices Chlor-XTRA™, Biopure MTAD Root Canal Cleanser, and Vista Rinse Plus.

<u>Differences between the subject device (V-Mix) and predicate devices (Chlor-XTRA™, Biopure MTAD Root Canal Cleanser, and Vista Rinse Plus)</u>

- Minor differences in indications for use between the subject device and the predicate devices (Chlor-XTRA™, Biopure MTAD Root Canal Cleanser, and Vista Rinse Plus). Based on V-Mix's dual action, V-Mix's indications for use are aligned with all the predicate devices.
- V-Mix and the predicate devices Biopure MTAD Root Canal Cleanser and Vista Rinse Plus all contain a chelating agent as an active ingredient. However, V-Mix contains PBTC and citric acid whereas the predicate devices, Biopure MTAD Root Canal Cleanser and Vista Rinse Plus, contain citric acid and EDTA, respectively.
    - Nevertheless, this difference does not raise any safety or efficacy concerns as PBTC, citric acid, and EDTA are all carboxylic acid chelating agents with a high affinity for calcium and all effectively remove the inorganic portion of smear layer.
- V-Mix is a standalone endodontic irrigant, whereas the primary predicate, Chlor-XTRA requires additional endodontic irrigants to thoroughly clean the root canal system.
    - Sodium hypochlorite (Chlor-XTRA™) is used for debridement but cannot be used as a standalone endodontic irrigant as it is not effective at removing smear layer.
    - V-Mix is used for debridement, cleansing, and removing the smear layer.
    - However, this difference does not raise any safety or efficacy concerns as the primary predicate device, Chlor-XTRA requires the subsequent use of a carboxylic acid chelating agent to remove the smear layer.

- V-Mix is a standalone endodontic irrigant, whereas the predicate devices, Biopure MTAD Root Canal Cleanser and Vista Rinse Plus require additional endodontic irrigants to thoroughly clean the root canal system.
    - Biopure MTAD Root Canal Cleanser and Vista Rinse Plus are used for cleansing and removing the smear layer but cannot be used as standalone endodontic irrigants.
    - V-Mix is used for debridement, cleansing, and removing the smear layer.
    - However, this difference does not raise any safety or efficacy concerns as the predicate devices, Biopure MTAD Root Canal Cleanser and Vista Rinse Plus, require the prior use of sodium hypochlorite-based solutions to debride the root canal.
- V-Mix has a shelf-life of 18 months, whereas the predicate devices (Chlor-XTRA™ and Vista Rinse Plus) have a shelf-life of 24 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 has labeling which adequately communicates shelf-life to the user.

Applicable Standards

- ISO 7405:2018 – Dentistry – Evaluation of Biocompatibility of Medical Devices Used In Dentistry
- ISO 10993-5:2009 – Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010 – Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 – Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity
- ISO 14971:2019 – 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 V-Mix:

- Analytical Testing
- Cytotoxicity Testing
- Shelf-Life Testing
- Bacteriostatic Testing
- Transit Testing
- SEM Evaluation
- Working Time
- Antimicrobial Performance
- Sensitization

- Intracutaneous Reactivity
- Acute Systemic Toxicity

8. Clinical Performance Testing and Compliance

Clinical performance is not deemed necessary.

9. Conclusion

V-Mix is to be marketed by Inter-Med / Vista Dental Products, 2200 South St. Ste. A., Racine, WI 53404, and is substantially equivalent to Chlor-XTRA™ (K082470), Biopure MTAD Root Canal Cleanser (K053167), and Vista Rinse Plus (K193409). The subject medical device has nearly identical intended use and technological characteristics as the predicate devices, and the device is substantially equivalent to the predicate devices.