September 9, 2020

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

Re: K193409
Trade/Device Name: Vista Rinse, Vista Rinse Plus
Regulatory Class: Unclassified
Product Code: KJJ
Dated: June 9, 2020
Received: June 12, 2020

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)*
K193409

Device Name
Vista Rinse and Vista Rinse Plus

Indications for Use *(Describe)*
Vista Rinse and Vista Rinse Plus are endodontic irrigating solutions that cleanse the root canal system by removing the smear layer after endodontic instrumentation.

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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K193409

510(k) Summary
for
Vista Rinse & Vista Rinse Plus

1. Applicant

Submitter's Name: Katherine Barry, MSc **Date Summary Prepared:** April 20, 2020

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

Phone: (262) 635-8956 **Email**: kbarry@vista-dental.com

Fax: (262) 636-9760

2. Device Name

Proprietary Name: Vista Rinse & Vista Rinse Plus
Common Name: Cleanser, Root Canal
Product Code: KJJ
Device Class: Unclassified

3. Predicate Devices

Q-Mix 2in1 Endodontic Irrigation Solution (K103244) by Dentsply Sirona
- Common Name: Cleanser, Root Canal
- Product Code: KJJ
- Device Class: Unclassified

PacEndo EDTA (K153528) by Pac-Dent International, Inc.
- Common Name: Cleanser, Root Canal
- Product Code: KJJ
- Device Class: Unclassified

4. Device Description

Vista Rinse and Vista Rinse Plus are endodontic irrigating solutions that cleanse the root canal system by removing the smear layer after endodontic instrumentation. Both medical devices are packaged in bottles. Clinical use of the medical devices requires the irrigant to be expelled from syringes through irrigation tips, which are class I medical devices per EIC product code (syringe, periodontic, endodontic, irrigating) and CFR regulation number 872.4565 and are 510(k) exempt.

5. Intended Use / Indication for Use

Vista Rinse and Vista Rinse Plus are endodontic irrigating solutions that cleanse the root canal system by removing the smear layer after endodontic instrumentation.

6. Technological Characteristics and Substantial Equivalence

	Subject Device: Vista Rinse and Vista Rinse Plus	**Primary Predicate Device: Q-Mix 2in1 Endodontic Irrigation Solution**	**Reference Predicate Device: PacEndo™ EDTA**
Manufacturer	Inter-Med / Vista Dental Products	Dentsply	Pac-Dent
510(k) Number	K193409	K103244	K153528
Common Name	Cleanser, Root Canal	Cleanser, Root Canal	Cleanser, Root Canal
Device Classification	Unclassified	Unclassified	Unclassified
Product Code	KJJ	KJJ	KJJ
Indication for Use	Vista Rinse and Vista Rinse Plus are endodontic irrigating solutions that cleanse the root canal system by removing the smear layer after endodontic instrumentation.	Q-Mix 2in1 Irrigation Solution is a premixed dual-action device that cleanses and disinfects the root canal system by removing the smear layer after endodontic instrumentation.	PacEndo™ EDTA is intended to facilitate removal of dentinal debris from the walls of root canals prior to obturation.
Where used	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
Anatomical site	Oral cavity	Oral cavity	Oral cavity
Physical Properties	Vista Rinse and Vista Rinse Plus are both clear, colorless, odorless aqueous solutions	Clear, colorless, odorless aqueous solution	Clear, colorless, odorless aqueous solution

	Subject Device: Vista Rinse and Vista Rinse Plus	Primary Predicate Device: Q-Mix 2in1 Endodontic Irrigation Solution	Reference Predicate Device: PacEndo™ EDTA
Chemical Properties	pH 7.0 – 8.5	pH 7.5 - 8.5[1]	pH 7.5
Mechanism of Action	The mechanical action of the solution moving in the root canal facilitates ease in the removal of debris, bacteria, and necrotic pulp tissue from the root canal.	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. The mode of action for the solution is that it disrupts the bacterial cell membrane, killing the cell to ensure that it cannot reproduce or grow.	The mechanical action of the solution moving in the root canal facilitates ease in the removal of debris, bacteria, and necrotic pulp tissue from the root canal.
Packaging Configuration	Both Vista Rinse and Vista Rinse Plus are packaged in the following configurations: 120mL and 480mL bottles	60mL and 480mL bottle	480 mL bottle
Sterility	Non-sterile	Non-sterile	Non-sterile
Active Ingredients	Vista Rinse: Ethylenediaminetetraacetic acid (EDTA) Vista Rinse Plus: Ethylenediaminetetraacetic acid (EDTA) Chlorhexidine digluconate (CHX)	Ethylenediaminetetraacetic acid (EDTA) Chlorhexidine digluconate (CHX) Cetrimonium bromide (CB)	Ethylenediaminetetraacetic acid (EDTA)
Shelf-Life	24 months	24 months	Unknown
Biocompatibility Testing Performed	Cytotoxicity	Cytotoxicity	Unknown
Prescription / OTC	Prescription	Prescription	Prescription

Similarities between the subject device (Vista Rinse) and predicate devices (Q-Mix and PacEndo EDTA)

- Besides tradenames, Vista Rinse has nearly identical indications for use as the primary predicate device, Q-Mix, and identical indications for use as the reference predicate device, PacEndo EDTA.

[1] The Q-Mix 510(k) (K103244) Executive Summary states "slightly basic" as a Chemical Property. In the cover letter and in the SDS for Q-Mix the pH is listed at 7.5 and 8.0, respectively. Furthermore, an additional lot of Q-Mix was evaluated by Inter-Med / Vista Dental and the pH was measured to be 8.5.

- Vista Rinse is classified under product code KJJ and shares the identical common name "Cleanser, Root Canal" as the predicate devices.
- Vista Rinse is nearly identical to the predicate devices, Q-Mix and PacEndo EDTA, as all products are EDTA-based aqueous liquids which aid in the cleansing of root canals during endodontic therapy.
- Vista Rinse is used in the same target population and anatomical site as the predicate devices.
- Identical to the predicate devices, Vista Rinse is for prescription use only by healthcare professionals.
- Vista Rinse is offered in the same configurations as the predicate devices (i.e. filled bottles).
- Vista Rinse has the same shelf-life as the predicate device Q-Mix 2in1 Endodontic Irrigation Solution (i.e. 24 months).
- Vista Rinse has identical technological characteristics to the predicate device (Q-Mix):
    - All medical devices contain an aqueous solution of EDTA.
    - All medical devices have similar pH values (i.e. slightly basic, 7.0 – 8.5).
    - Identical results to the primary predicate device, Q-Mix, within cytotoxicity testing at 24 hours and smear layer removal.

<u>Similarities between the subject device (Vista Rinse Plus) and predicate devices (Q-Mix and PacEndo EDTA)</u>

- Besides tradenames, Vista Rinse Plus has nearly identical indications for use as the predicate devices, Q-Mix and PacEndo EDTA.
- Vista Rinse Plus is classified under product code KJJ and shares the identical common name "Cleanser, Root Canal" as the predicate devices.
- Vista Rinse Plus is nearly identical to the predicate devices Q-Mix and PacEndo EDTA, as all products are EDTA-based aqueous liquids containing surfactants which aid in the cleansing of root canals during endodontic therapy.
- Vista Rinse Plus is used in the same target population and anatomical site as the predicate devices.
- Identical to the predicate devices, Vista Rinse Plus is for prescription use only by healthcare professionals.
- Vista Rinse Plus is offered in the same configurations as the predicate devices (i.e. filled bottles).
- Vista Rinse Plus has the same shelf-life as the predicate device Q-Mix 2in1 Endodontic Irrigation Solution (i.e. 24 months).
- Vista Rinse Plus has identical technological characteristics to the predicate device:
    - Vista Rinse Plus and Q-Mix contain an aqueous solution of EDTA and chlorhexidine digluconate.
    - All medical devices have similar pH values (i.e. slightly basic, 7.0 – 8.5).
    - Identical results to the primary predicate device, Q-Mix, within cytotoxicity testing at 24 hours and smear layer removal.

Vista Rinse & Vista Rinse Plus share similar intended uses, technical characteristics, and methods of application to the predicate devices (Q-Mix and PacEndo EDTA). Therefore, Vista Rinse & Vista Rinse Plus pose no additional safety risks or efficacy concerns.

Differences between the subject device (Vista Rinse) and predicate devices (Q-Mix and PacEndo EDTA)

- Vista Rinse is packaged in 120mL and 480mL bottles, whereas the predicate devices, Q-Mix and PacEndo EDTA are packaged in 60mL and 480mL bottles and 480mL bottles, respectively.
    - The difference of 120mL vs 60mL bottles does not raise any safety or efficacy risks as this is simply user preference and has no implications on risk or efficacy. A clinical user of the predicate device could use two 60mL bottles in place of one 120mL bottle of the subject device.
- While the predicate devices, Q-Mix and PacEndo EDTA, have a pH of 7.5 – 8.5 and 7.5, respectively, Vista Rinse has a pH range of 8.0 to 8.5. This has no impact on safety or efficacy as the pH ranges of the subject device and predicate devices overlap. Furthermore, according to Nikiforuk and Sreebny[2] at a pH above 6, calcium is strongly chelated by EDTA.
- While the predicate devices, Q-Mix and PacEndo EDTA, contain an aqueous solution of EDTA and surfactants, Vista Rinse contains an aqueous solution of EDTA without the addition of surfactants. The lack of surfactants has no impact on safety or efficacy, as 17% EDTA has been used for over 60 years as the gold standard irrigant for the removal of smear layer.

Differences between the subject device (Vista Rinse Plus) and predicate devices (Q-Mix and PacEndo EDTA)

- Vista Rinse Plus is packaged in 120mL and 480mL bottles, whereas the predicate devices, Q-Mix and PacEndo EDTA are packaged in 60mL and 480mL bottles and 480mL bottles, respectively.
    - The difference of 120mL vs 60mL bottles does not raise any safety or efficacy risks as this is simply user preference and has no implications on risk or efficacy. A clinical user of the predicate device could use two 60mL bottles in place of one 120mL bottle of the subject device.
- While the predicate devices, Q-Mix and PacEndo EDTA, have a pH of 7.5 – 8.5 and 7.5, respectively, Vista Rinse Plus has a pH range of 7.0 to 8.0. This has no impact on safety or efficacy as the pH ranges of the subject device and predicate devices overlap. Furthermore, according to Nikiforuk and Sreebny[2] at a pH above 6, calcium is strongly chelated by EDTA.
- While the predicate devices, Q-Mix and PacEndo EDTA, contain an aqueous solution of EDTA and surfactants, Vista Rinse Plus contains an aqueous solution of EDTA with a different blend of surfactants. The different blend of surfactants has no implications on safety or efficacy, as all surfactants have been used in previously cleared 510(k)s.

[2] Nikiforuk G, Sreenby L. Demineralization of hard tissues by organic chelating agents at neutral pH. *J Dent Res*. 1953;32(6):859-867. doi:10.1177/00220345530320061401

- At 72 hours, Vista Rinse Plus proved to be less cytotoxic than Q-Mix at dilutions of 1:16 and 1:64. This does not raise any concerns of safety or efficacy.

Applicable Standards

- ISO 10993-5:2009 – Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- 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 Vista Rinse & Vista Rinse Plus to the primary predicate device, Q-Mix:

- Analytical Testing
  - Testing verified manufacturing of Vista Rinse & Vista Rinse Plus. Results from testing are commensurate with the predicate device, supporting substantial equivalence of the subject device to an existing commercialized device.
- Cytotoxicity Testing
  - Vista Rinse & Vista Rinse Plus exhibited the same cytotoxicity results at 24 hours as the predicate device (Q-Mix) sold for the same intended use.
  - This testing confirms that the subject device is substantially equivalent to the predicate device. Combined with DHF-10008-BS, 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 Rinse & Vista Rinse Plus. Real time aging is being performed on Vista Rinse & Vista Rinse Plus to support shelf life during typical storage conditions.
- SEM Evaluation & Calcium Chelation Testing
  - Testing verified that Vista Rinse & Vista Rinse Plus satisfactorily performed as root canal cleansers via SEM imaging. Substantial equivalence to the predicate device, Q-Mix, is supported as the subject medical devices have calcium chelation characteristics equal to or better than the predicate device.

8. Clinical Performance Testing and Compliance

Clinical performance is not deemed necessary.

9. Conclusion

Vista Rinse & Vista Rinse Plus have similar intended uses and technological characteristics as the predicate devices, and all devices are suitable when used for their described indications. Therefore, Inter-Med concludes that Vista Rinse & Vista Rinse Plus are substantially equivalent to the predicate devices, Q-Mix and PacEndo EDTA.