August 18, 2021

Inter-Med / Vista Dental
Brett Arand
Senior Product Development Engineer
2200 South Street
Racine, Wisconsin 53404

Re: K211813
Trade/Device Name: Triton
Regulatory Class: Unclassified
Product Code: KJJ
Dated: July 15, 2021
Received: July 20, 2021

Dear Brett Arand:

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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT 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)*

K211813

Device Name

Triton

Indications for Use *(Describe)*

Triton is used for debridement, removing the smear layer, and cleansing the root canal system.

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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SECTION 5 – 510K SUMMARY-K211813

Applicant

Inter-Med / Vista Dental Products
2200 South Street
Racine, WI, USA 53404
Contact Person: Brett Arand

Telephone Number: (262) 633-0755
Fax Number: (262) 636-9760
Email: barand@vista-dental.com

Date Prepared: June 9th, 2021
Prepared By: Brett Arand

Device Name

Proprietary Name: Triton
Common Name: Cleanser, Root Canal
Product Code: KJJ
Device Class: Unclassified

Predicate Device

V-Mix (K193357) by Inter-Med / Vista Dental Products
- Common Name: Cleanser, Root Canal
- Product Code: KJJ
- Device Class: Unclassified

Device Modification Summary

Triton, subject of the present special 510(k) notification, is a two-part, dual-action root canal cleanser. Previously, the product under the trade name V-Mix was approved under 510(k) number K193357. Triton consists of the same irrigating solution with no changes to formulation however it is packaged in a 2-part bottle instead of 2-part syringes. No changes were made to specific technical characteristics of the product. Labeling only changed as it corresponds to the change in packaging, i.e. a bottle and cap instead of syringe and tip. As Triton is equivalent to Vista's own predicate device V-Mix currently marketed in the U.S., a special 510(k) is the most appropriate premarket notification. The change from the name "V-Mix" to "Triton" is purely a branding change.

Device Description

Triton is a two-part, dual-action root canal cleanser. Triton Part A is an aqueous solution that contains carboxylic acid chelating agents and surfactants. Triton Part 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.

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

Indications for Use

Triton is used for debridement, removing the smear layer, and cleansing the root canal system.

Technological Characteristics

All of the components found in Triton 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 Triton for the indicated uses.

Device Comparison

Please reference Table 5-1 below for a comparison of Triton to the previously submitted V-Mix Device.

Table 5-1: Comparison of the existing cleared 510(k) (V-Mix, K193357) to this special 510(k) submission.

	Predicate Device	**Subject Device**
Trade Name	V-Mix	Triton
510(k) Number	K193357	k211813
Common Name	Cleanser, Root Canal	Cleanser, Root Canal
Device Classification	Unclassified	Unclassified
Product code	KJJ	KJJ
Indications for Use	V-Mix is used for debridement, removing the smear layer, and cleansing the root canal system.	Triton is used for debridement, removing the smear layer, and cleansing the root canal system.
Target Users	Licensed Dental Professionals	Licensed Dental Professionals
Anatomical Site	Oral cavity / Isolated tooth	Oral cavity / Isolated tooth
Part A Description	Aqueous solution that contains carboxylic acid chelating agents and surfactants	Aqueous solution that contains carboxylic acid chelating agents and surfactants

Part B Description	Aqueous solution that contains sodium hypochlorite	Aqueous solution that contains sodium hypochlorite
Packaging	10mL pre-filled dual cartridge syringe with applicator tip. Part A and Part B are mixed in the tip as it is dispensed.	Dual 8oz bottles with a dispensing cap. Standard syringes attach to a luer activated valve on the dispensing cap. Fluid is drawn into the syringe from Bottle A and Bottle B simultaneously and equally.
Shelf Life	9 Months	30 Months
Biocompatibility Testing/Analysis Performed*	ISO 7405:2018 ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-11:2017	ISO 7405:2018 ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-11:2017
Risk	Acceptable, risk management has mitigated all identified risks to acceptable levels; benefits of the device outweigh any residual risks	Acceptable, risk management has mitigated all identified risks to acceptable levels; benefits of the device outweigh any residual risks
Prescription/OTC	Prescription	Prescription

***Note**: As the formula is not changing, reference is made to the cleared 510(k) K193357 Section 15 – Biocompatibility which contains all the ISO 10993 biocompatibility test reports.

Similarities between the subject device (Triton) and the already cleared device (V-Mix, K193357)

- The formula is identical between Triton and the already cleared device, V-Mix.
- Triton has identical indications for use as the already cleared device, V-Mix.
- Triton is classified under product code KJJ and shares the identical common name "Cleanser, Root Canal" as the already cleared device, V-Mix.
- Identical to the already cleared device, Triton is a non-sterile device, V-Mix.
- Identical to the already cleared device, syringes and endodontic irrigating tips are used to deliver the device to the root canal space.

Triton is identical to the already cleared device, V-Mix, in every aspect besides the differences discussed below.

Differences between the subject device (Triton) and the already cleared device (V-Mix, K193357)

- Triton is packaged in a 2-part bottle, whereas the already cleared device, V-Mix, was packaged in a 2-part syringe.
    - This difference does not raise any concerns as test reports within the product's design history file (DHF) support and confirm the packaging compatibility.
    - Furthermore, the 2-part bottle of Triton is nearly analogous to the 2-part syringe packaging of V-Mix but just in "bulk packaging" for economical efficiencies to the user.

    - Lastly, the 2-part bottle of Triton is only a packaging configuration for bulk storage and sale of the product, as a syringe and endodontic irrigating tip is still required for clinical use in the root canal space which is commensurate with all existing endodontic irrigants already on the market. Therefore, the packaging change does not introduce any changes to clinical utility or use of the Triton device.
    - As such, Inter-Med confirms Triton remains substantially equivalent to the cleared device.

- Triton has a 30 month shelf-life, whereas the already cleared device, V-Mix, has a 9 month shelf-life.
    - This difference does not raise any concerns as test reports within the product's design history file (DHF) support and confirm the designated shelf-life durations.
    - As such, Inter-Med confirms Triton remains substantially equivalent to the cleared device.

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

Non-Clinical Performance Testing and Compliance

The following non-clinical tests were conducted to evaluate the functionality, performance, safety, and substantial equivalence of Triton:

- Shelf-Life Testing
- Working Time
- Material Compatibility
- Packaging Function (Equal Draw Testing)

Clinical Performance Testing and Compliance

Clinical performance is not deemed necessary.

Conclusion

Triton is to be marketed by Inter-Med / Vista Dental Products, 2200 South St. Ste. A., Racine, WI 53404, and is substantially equivalent to V-Mix (K193357).