August 27, 2024

Inter-Med, Inc.
Brett Arand
Sr. Product Development Engineer
2200 South Street
Racine, Wisconsin 53575

Re: K241354
Trade/Device Name: Sealer Solvent
Regulatory Class: Unclassified
Product Code: KJJ
Dated: May 13, 2024
Received: July 31, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, MChE, RAC, CQIA
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)*
K241354

Device Name
Sealer Solvent

Indications for Use *(Describe)*

Sealer Solvent, a root canal cleanser, is intended to irrigate, cleanse, and debride root canal systems including the removal of foreign material and debris during root canal therapy.

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
Sealer Solvent

K241354

Updated Per Hold Letter Received July 12, 2024

1. 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: July 29th, 2024
Prepared By: Brett Arand

2. Device Name

Proprietary Name: Sealer Solvent
Classification Name: Cleanser, root canal
CRF Number: NA
Product Code: KJJ
Device Class: Unclassified

3. Predicate Device

Sealer Solvent is substantially equivalent to the legally marketed device Citric Acid 20% Solution (K063703), submitted by Ultradent Products, Inc. and cleared on December 21st, 2006, product code KJJ.

4. Device Description

The Sealer Solvent presents a clinically effective way to aid in removal of bioceramic root canal sealers during endodontic retreatment procedures. Sealer Solvent is an aqueous-based irrigant that is delivered via syringe and needle tip while instrumenting the canal after any gutta percha is removed. Sealer solvent works to soften and dissolve the sealer to be flushed out or removed with files.

Although Sealer Solvent has been designed for use as a retreatment irrigant, it may be used during traditional endodontic non-retreatment procedures as an endodontic irrigant (i.e. root canal

cleanser) to help remove inorganic solids from canal walls, such as smear layer and calcium hydroxide, prior to obturation.

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

5. Intended Use

Sealer Solvent is a device that cleanses root canal systems by irrigating root canals.

6. Indication for Use

Sealer Solvent, a root canal cleanser, is intended to irrigate, cleanse, and debride root canal systems including the removal of foreign material and debris during root canal therapy.

7. Technological Characteristics and Substantial Equivalence

The technological characteristics of the Sealer Solvent are similar to the predicate device Ultradent Citric Acid Irrigant 20% (K063703). The Sealer Solvent and the predicate device Ultradent Citric Acid Irrigant 20% (K063703) perform the same function, which is to cleanse the root canal. A comprehensive comparison of technological characteristics and substantial equivalence between the devices is provided below.

Table 5-1: Predicate and Proposed Device Comparison Table

	Proposed Device **Sealer Solvent**	**Predicate Device** **20% Citric Acid Irrigant**	**Reference Device** **EDS Combo-Rinse**	**Reference Device** **Endocyn Root Canal Irrigation Solution**
Manufacturer	Inter-Med, Inc / Vista Apex	Ultradent, Inc.	Essential Dental Systems, Inc.	Oculus Innovative Sciences
510(k)	K241354 Subject of this 510(k) submission	K063703	K140846	K141352
Trade name	Sealer Solvent	Citric Acid 20%	EDS Combo-Rinse	Endocyn Root Canal Irrigation Solution

	Proposed Device Sealer Solvent	Predicate Device 20% Citric Acid Irrigant	Reference Device EDS Combo-Rinse	Reference Device Endocyn Root Canal Irrigation Solution
Class	Unclassified	Unclassified	Unclassified	Unclassified
FDA Classification Name and CFR Number	Cleanser, Root Canal	Cleanser, Root Canal	Cleanser, Root Canal	Cleanser, Root Canal
Product code	KJJ	KJJ	KJJ	KJJ
Intended Use	Sealer Solvent is a device that cleanses root canal systems by irrigating root canals.	Facilitates removal of calcium hydroxide from canal walls, and functions as a mild etchant/conditioner for smear layer removal.	EDS Combo-Rinse is a device that cleanses root canal systems by irrigating root canals.	Endocyn Root Canal Irrigation Solution is intended to irrigate, cleanse, and debride root canal systems including the removal of foreign material and debris during root canal therapy. It is also intended to provide for lubrication and irrigation during root canal instrumentation.
Indications for Use	Sealer Solvent, a root canal cleanser, is intended to irrigate, cleanse, and debride root canal systems including the removal of foreign material and debris during root canal therapy.	Citric Acid 20%, a root canal cleanser, is intended to etch root canal walls just prior to obturation to allow an optimum seal.	EDS Combo-Rinse is intended to cleanse root canal systems by irrigating root canals.	
Target Users	Licensed Dental Professionals	Licensed Dental Professionals	Licensed Dental Professionals	Licensed Dental Professionals
Intended Population	Patients undergoing endodontic root canal	Patients undergoing endodontic root canal procedures	Patients undergoing endodontic root canal procedures	Patients undergoing endodontic root canal procedures

	Proposed Device Sealer Solvent	Predicate Device 20% Citric Acid Irrigant	Reference Device EDS Combo-Rinse	Reference Device Endocyn Root Canal Irrigation Solution
	procedures, including retreatment procedures			
Anatomical site	Oral cavity / Isolated tooth	Oral cavity / Isolated tooth	Oral cavity / Isolated tooth	Oral cavity / Isolated tooth
Active Ingredients (bold text added to highlight similarities in composition between subject device and predicate devices)	**Citric Acid at 20%**	**Citric Acid at 20%**	EDTA (a type of chelator)	Sodium hypochlorite
Inactive Ingredients	Proprietary chelators & surfactants, pH modifier, **water**	Polydimethyl siloxane, orange colorant, **water**	Unknown ingredients, **Water**	**Water**
pH	2-5	1.7	Unknown	Unknown
Properties	Clear, water-like consistency	Orange-tinted, slightly thickened	Clear, colorless, water-like consistency	Clear, colorless, water-like consistency
Mechanism of Action /	Sealer Solvent contains citric acid and other ingredients that have been specifically	Citric acid helps remove calcium hydroxide, and functions as a mild etchant/conditioner for	Chelator helps remove smear layer via chelation	Helps debride and cleanse the root canal

	Proposed Device Sealer Solvent	Predicate Device 20% Citric Acid Irrigant	Reference Device EDS Combo-Rinse	Reference Device Endocyn Root Canal Irrigation Solution
Principle of Operation	formulated to dissolve inorganic materials from root canal walls	smear layer removal via chelation		
Application method	Filled into syringes and delivered via choice of dental irrigation tip	Filled into syringes and delivered via choice of dental irrigation tip	Filled into syringes and delivered via choice of dental irrigation tip	Filled into syringes and delivered via choice of dental irrigation tip
Packaging & Storage	• 4 oz (118mL) refill bottle, no special storage conditions.	• 30 mL refill syringe, no special storage conditions.	• Bottle	• Bottle
Nature of Body Contact (ISO 7405:2018)	External communicating device with limited (≤24 hour) contact time	External communicating device with limited (≤24 hour) contact time	External communicating device with limited (≤24 hour) contact time	External communicating device with limited (≤24 hour) contact time
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Shelf-Life	Shelf life is 36 months	Shelf life is 30+ months	Unknown	Unknown
Cytotoxicity Testing / Analysis Performed	All components that make patient contact have been evaluated according to ISO 7405 / ISO 10993-1 and meet requirements	Meets Requirements	Meets Requirements	Meets Requirements

	Proposed Device Sealer Solvent	Predicate Device 20% Citric Acid Irrigant	Reference Device EDS Combo-Rinse	Reference Device Endocyn Root Canal Irrigation Solution
Prescription / OTC	Prescription	Prescription	Prescription	Prescription
Standards	ISO 7405:2018 ISO 10993-1:2018 ISO 10993-5:2009 ISO 14971:2019 ISO 15223-1:2021 ISO 11014:2009 ISO 20417:2021	Unknown	Unknown	Unknown

Applicable Standards

ISO 7405:2018	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
ISO 10993-1:2018	Biological evaluation of medical devices
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
ISO 15223-1:2021	Symbols to be used with information to be supplied by the manufacturer
ISO 11014:2009	Safety data sheet for chemical products
ISO 20417:2021	Medical devices Information to be supplied by the manufacturer

8. Non-Clinical Performance Testing and Compliance

The technological characteristics of Sealer Solvent are very similar to the predicate Citric Acid Irrigant 20% (K063703). Sealer Solvent and the predicate Citric Acid Irrigant 20% (K063703) are both root canal cleansers that perform similar functions. Sealer Solvent removes inorganic solids from the root canal walls, such as smear layer, bioceramic

sealer, MTA, or calcium hydroxide, while Citric Acid Irrigant 20% (K063703) removes inorganic solids found in smear layer. The following performance tests were conducted as part of design verification:

- Dissolution testing
- In-Vitro Canal Performance Testing
- Shelf-Life Verification
- Biocompatibility Analysis
- Cytotoxicity testing
- Anti-microbial testing
- Transit Testing

9. Clinical Performance Data

Clinical performance testing has not been performed for Sealer Solvent.

10. Conclusion as to Substantial Equivalence

The Sealer Solvent is to be marketed by Inter-Med, Inc., 2200 South Street, Racine, WI 53404, and is substantially equivalent to the predicate device, Ultradent Citric Acid 20%. The subject medical device has very similar indications for use, and similar technical characteristics, principles of operation and performance characteristics to the predicate device. The Sealer Solvent is safe and effective when used for the described indications. Any differences between the subject medical device and predicate medical device have been fully addressed and do not raise any additional safety or efficacy concerns. Therefore, it has been concluded that the Sealer Solvent is substantially equivalent to the predicate device, Ultradent Citric Acid 20%.