November 21, 2022

Inter-Med, Inc.
Alex Johnson
Dir. Engineering, Regulatory & Quality
2200 South St
Racine, Wisconsin 53404

Re: K221811
Trade/Device Name: Vista BC Sealer
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: October 14, 2022
Received: October 25, 2022

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,

Michael E. Adjodha -S

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)*

K221811

Device Name
Vista BC Sealer

Indications for Use *(Describe)*

• Permanent obturation of the root canal following vital pulp-extirpation.
• Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.

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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K221811

510(k) Summary
for
Vista BC Sealer

1. Applicant

Submitter's Name: Alex Johnson
Khongchee Xiong
Sara Travia

Date Summary Prepared: October 14, 2022

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

Contact Person: Alex Johnson, MSc

Email: ajohnson@vista-dental.com

Phone: (262) 631-5306

Fax: (262) 636-9760

2. Device Name

Proprietary Name: Vista BC Sealer
Common Name: Root canal filling
Product Code: KIF
Device Class: Class 2

3. Predicate Device

Primary Predicate Device ENDOSEAL MTA (K170175) by Maruchi, Inc.

- Common Name: Root canal filling
- Product Code: KIF
- Device Class: Class 2

Reference Device iRootSP (K080917) by Innovative BioCeramix, Inc.

4. Device Description

Vista BC Sealer is a convenient premixed ready-to-use injectable white hydraulic cement paste developed for permanent root canal filling and sealing applications. Vista BC Sealer is an insoluble, radiopaque material based on a calcium sodium phosphosilicate and calcium aluminate cement composition, which requires the presence of water to set and harden. Vista BC Sealer does not appreciably shrink during setting and demonstrates excellent physical properties. Vista BC Sealer is packaged in a pre-loaded syringe and supplied with disposable single use application tips.

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

5. Intended Use / Indication for Use

- Permanent obturation of the root canal following vital pulp-extirpation.
- Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.

6. Technological Characteristics and Substantial Equivalence

Characteristic	**Proposed Device**	**Primary Predicate Device**	**Reference Device**
Trade Name	Vista BC Sealer	ENDOSEAL MTA	iRoot SP
510(k) Number	Pending (subject device for this 510(k) submission)	(K170175)	(K080917)
Common name	Root Canal Filling	Root Canal Filling	Root Canal Filling
Product Code	KIF	KIF	KIF
Manufacturer	Inter-Med Inc. / Vista Dental Products	MARUCHI	Innovative BioCeramix, Inc.
Device Description	Vista BC Sealer is a ready-to-use injectable white hydraulic cement paste suitable for permanent root canal filling and sealing of the entire root canal. It is packaged in a preloaded syringe, which allows for complete filling of the root canal including accessory and lateral canals.	ENDOSEAL MTA is an endodontic sealer based on MTA, providing a root canal filling. It is premixed and pre-loaded in a syringe, which allows a complete filling of the entire root canal including accessory and lateral canals.	iRoot SP Root Canal Sealer (IRoot SP) is a ready-to-use injectable white hydraulic cement paste developed for permanent root canal filling and sealing applications. iRoot SP is an insoluble, radiopaque and aluminum-free material based on a calcium silicate composition, which requires the presence of water to set and harden.

Characteristic	Proposed Device	Primary Predicate Device	Reference Device
Trade Name	Vista BC Sealer	ENDOSEAL MTA	iRoot SP
			iRoot SP is packaged in a preloaded syringe and is supplied with disposable Intra Canal Tips.
Intended Population	Dental and Endodontic offices	Dental and Endodontic offices	Dental and Endodontic offices
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity
Composition (bold text added to highlight similarities in composition between subject device and predicate / reference devices)	**Calcium aluminates, Zirconium oxide,** Calcium sodium phosphosilicate, **Thickening agent (fumed silica),** Lithium chloride, Propylene glycol	Calcium silicates, **Calcium aluminates, Zirconium oxide,** Calcium sulfates, **Thickening agent**	**Zirconium oxide,** Calcium silicate, Calcium hydroxide, Calcium phosphate monobasic, Propylene glycol, **Thickening agent**
Principle of operation	Vista's BC Sealer is an insoluble and radiopaque root canal sealer which requires the presence of water to set and harden. Upon placement of material into the root canal, the moisture present from surrounding tissues helps to initiate a setting reaction within the material and eventually solidifying into a hard structure.	The inside of the root canal system has high humidity due to residual moisture in the dentinal tubules. MTA solidifies into a hard structure by absorbing the moisture from the surrounding tissue. Calcium hydroxide is produced due to the hydration reaction of the calcium silicates increasing the pH of the medium.	iRoot SP is an insoluble and radiopaque root canal sealer which requires the presence of water to set and harden.
Indications for use	Permanent obturation of the root canal following vital pulp-extirpation. Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.	Permanent obturation of the root canal following vital pulp-extirpation. Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.	Permanent obturation of the root canal following vital pulp-extirpation. Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings. iRoot SP is suitable for use in the single cone and lateral condensation technique.
Delivery form	Single paste	Single paste	Single paste
Design	Pre-loaded syringe, Disposable single use application tips (i.e.	Pre-loaded syringe, Disposable Intra Canal Tips	Pre-loaded syringe, Disposable Intra Canal Tips

Characteristic	Proposed Device	Primary Predicate Device	Reference Device
Trade Name	Vista BC Sealer	ENDOSEAL MTA	iRoot SP
	identical to Intra Canal Tips)		
Nature of Contact	Category: External communicating device Contact: Tissue, bone and dentin Contact Duration: C - Permanent (>30 days)	Category: External communicating device Contact: Tissue, bone and dentin Contact Duration: C - Permanent (>30 days)	Category: External communicating device Contact: Tissue, bone and dentin Contact Duration: C - Permanent (>30 days)
Set Time	≤ 90 minutes	12.31 minutes	240-600 minutes
Sterile	Non-sterile	Non-sterile	Non-sterile
Shelf Life	2 years	2 years	2 years
Standards	ISO 7405 ISO 6876 ISO 10993-5 ISO 80369-7 ISO 14971 ISO 10993-10 ISO 10993-11 ISO 10993-3	ISO 6876	ISO 6876

Similarities between the subject device (Vista BC Sealer) and the predicate and reference devices (ENDOSEAL MTA and iRoot SP)

- Vista BC Sealer is classified under product code KIF and shares the identical common name "Resin, Root Canal Filling" as the predicate and reference devices.
- Vista BC Sealer has identical indications for use as the predicate device.
- Vista BC Sealer has the same contact duration (Permanent, >30 days) as the predicate and reference devices.
- Vista BC Sealer has identical mode of operation as the predicate and reference devices since these products are hydraulic cements which that require the presence of water to set and harden.
- Vista BC Sealer is used in the same target population and anatomical site as the predicate and reference devices.
- Vista BC Sealer is offered in the same configurations as the predicate and reference devices (i.e. pre-loaded syringes with disposable single use application tips / intra canal tips)
- Vista BC Sealer has an identical shelf life as the predicate and reference device (i.e. 2 years)
- Vista BC Sealer has identical technological characteristics to the predicate device:
    - Chemical composition:

    - Both devices are composed of calcium-based cement, specifically calcium aluminates
    - Both use zirconium oxide as its radiopacifying agent
    - Both use thickening agents
  - Both devices have an alkaline pH.
  - Both devices are compliant with ISO 6876.
  - Both devices do not appreciably shrink while setting and hardening.

Vista BC Sealer shares similar intended uses, technical characteristics, and methods of application to the predicate and reference devices (ENDOSEAL MTA and iRoot SP, respectively). Therefore, Vista's BC Sealer is substantially equivalent to these devices and poses no additional safety risks or efficacy concerns.

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

Differences between the subject device (Vista BC Sealer) and the predicate and reference devices (ENDOSEAL MTA and iRoot SP)

- Vista BC Sealer has a set time of ≤90 minutes whereas ENDOSEAL MTA and iRoot SP have a set time of 12 minutes and 240-600 minutes, respectively.
  - This difference does not raise any safety or efficacy concerns since the set time of Vista's BC Sealer is between the predicate and reference devices' set time.
  - Therefore, this difference does not raise any additional safety or efficacy concerns and the subject device remains substantially equivalent to the predicate device.
- Vista BC Sealer has a slightly different formulation than the predicate device ENDOSEAL MTA. Specifically, Vista BC Sealer contains a calcium sodium phosphosilicate as an added filler as well as an accelerator for helping speed the cementation reaction, whereas ENDOSEAL MTA contains calcium silicates and calcium sulfates which participate in the cementation reaction.
  - This difference does not raise any safety or efficacy concerns since all ingredients are safe for their intended use as evident through testing and literature references.
  - Therefore, this difference does not raise any additional safety or efficacy concerns and the subject device remains substantially equivalent to the predicate device.

Applicable Standards

- ISO 7405:2018 – Dentistry – Evaluation of Biocompatibility of Medical Devices Used in Dentistry
- ISO 6876:2012 – Dentistry – Root Canal Sealing Materials
- ISO 10993-5:2009 – Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- ISO 80369-7 – Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

- 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 BC Sealer to ENDOSEAL MTA:

- Shelf-Life Testing
  - Through accelerated shelf life testing, Vista BC Sealer was found to have a shelf-life of two years. Real time aging is being performed on Vista BC Sealer to support shelf life during typical storage conditions.
- ISO 6876 Testing
  - Flow testing, set time testing, film thickness testing, solubility and degradation testing, and radiopacity testing were completed on Vista BC Sealer and ENDOSEAL MTA (predicate device) following methods detailed in ISO 6876.
  - For all testing, Vista BC Sealer was found to be performed very similarly to the predicate device, ENDOSEAL MTA, thereby confirming substantial equivalence.
- Transit Testing
  - This test confirms that the packaging configurations are sufficient and withstand simulated transit conditions. Moreover, the products performed satisfactory post-transit, which confirms that transit did not have a negative effect on the products themselves.
- Microbiological Testing
  - Contamination risks from manufacturing are mitigated as Vista BC Sealer exhibits bactericidal properties. Furthermore, these results help to support shelf stability and multiple use of non-patient contacting materials, such as the syringes, as any introduced microbes will not remain viable within the medical device.
- Cytotoxicity Testing
  - Vista BC Sealer was found to yield equivalent, or better, cytotoxicity results compared to the predicate device, ENDOSEAL MTA.
- Sensitization Testing
  - Vista BC Sealer showed no evidence of causing delayed dermal contact sensitization in guinea pigs. Therefore, it is confirmed Vista BC Sealer is not considered a sensitizer. As Vista BC Sealer passed this biocompatibility test, comparison to the predicate device is not deemed necessary.
- Intracutaneous Irritation Testing
  - Vista BC Sealer does not cause intracutaneous irritation and is not considered an irritant. As Vista BC Sealer passed this biocompatibility test, comparison to the predicate device is not deemed necessary.
- Acute Systemic Toxicity Testing

- All animals evaluated in this study showed no mortality or evidence of systemic toxicity from systemic exposure to Vista BC Sealer. All animal displayed normal behaviors and displayed a positive weight gain. Therefore, Vista BC Sealer is not systemically toxic and showed no evidence of systemic toxicity. As Vista BC Sealer passed this biocompatibility test, comparison to the predicate device is not deemed necessary.

- Genotoxicity Testing
  - Vista BC Sealer showed no signs of mutagenicity during tests. Therefore, Vista BC sealer is confirmed as non-mutagenic. As Vista BC Sealer passed this biocompatibility test, comparison to the predicate device is not deemed necessary.

8. Clinical Performance Testing and Compliance

Clinical performance is not deemed necessary.

9. Conclusion

Vista BC Sealer is to be marketed by Inter-Med, Inc., 2200 South St., Racine, WI 53404, and is substantially equivalent to ENDOSEAL MTA (K170175). The subject medical device has a nearly identical intended use and technological characteristics as the predicate device. Any differences between the subject medical device and predicate medical device do not significantly alter the product's use and do not result in unacceptable or unnecessary risks to the patients or users. Therefore, Inter-Med concludes that Vista BC Sealer is substantially equivalent to the predicate device, ENDOSEAL MTA, and the product is safe and effective for its intended use.