August 28, 2024

Inter-Med, Inc.
Alex Johnson
VP of Engineering, Regulatory & Quality
2200 South Street
Racine, Wisconsin 53404

Re: K241457
Trade/Device Name: Vista BC Putty
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: May 22, 2024
Received: May 23, 2024

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 (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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241457

Device Name

Vista BC Putty

Indications for Use *(Describe)*

- Repair of Root Perforation
- Repair of Root Resorption
- Root End Filling
- Apexification
- Pulp Capping

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for Vista BC Putty

K241457

1. Applicant

Submitter's Name: Alex Johnson
Khongchee Xiong

Date Summary Prepared: March 28, 2024

Address: Inter-Med, Inc. / Vista Apex
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 Putty
Common Name: Root canal filling material
Product Code: KIF
Device Class: Class 2

3. Predicate Device

Primary Predicate Device MTA 2.3 (Design 2) by Avalon Biomed, Inc.

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

Reference Device #1 iRoot FS by Innovative BioCeramix, Inc.

- Common Name: Root canal filling material
- Product Code: KIF

- Device Class: Class 2

Reference Device #2 Vista BC Sealer (K221811) by Inter-Med, Inc.
- Common Name: Root canal filling material
- Product Code: KIF
- Device Class: Class 2

4. Device Description

Vista BC Putty is a hydraulic, ready-to-use injectable bioceramic, bioactive root repair paste developed for permanent root canal repair of root perforation and root resorption, and root end filling, apexification and pulp capping applications. Vista BC Putty 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 Putty does not appreciable shrink during setting and demonstrates excellent physical properties.

1.0g of Vista BC Putty is packaged in a 1.2mL syringe. Vista BC Putty is for prescription use (Rx) only.

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

5. Intended Use / Indication for Use

- Repair of Root Perforation
- Repair of Root Resorption
- Root End Filling
- Apexification
- Pulp Capping

6. Technological Characteristics and Substantial Equivalence

Characteristic	Proposed Device	Predicate Device	Reference Device #1	Reference Device #2
510(k) Number	Pending (subject device for this 510(k) submission)	(K181917)	(K102867)	(K221811)
Common Name	Root Canal Filling	Root Canal Filling	Root Canal Filling	Root Canal Filling
Product Code	KIF	KIF	KIF	KIF
Trade Name	Vista BC Putty	MTA 2.3 (Design 2)	iRoot FS	Vista BC Sealer

Manufacturer	Inter-Med, Inc.	Avalon Biomed	Innovative BioCeramix, Inc.	Inter-Med, Inc.
Device Description	Vistas BC Putty is a hydraulic, ready-to-use injectable bioceramic, bioactive root repair paste developed for permanent root canal repair of root perforation and root resorption, and root end filling, apexification and pulp capping applications.	The MTA2.3 ROOT & PULP MATERIALS are designed and developed for dental clinicians to use in contact with vital pulp tissue and periradicular tissue, including sealing and obturation of root canals. The materials can be used for dental procedures contacting pulpal or periradicular tissue such as: pulp capping, cavity lining, base material in a cavity, pulpotomies, root-end filling, apexification, perforation repair, root resorption, and obturation (pulpectomy) including root canal sealing.	iRoot FS Injectable Root Canal Repair Filling Material is a convenient ready-to-use fast setting white hydraulic premixed bioceramic pasted developed for permanent root canal repair of root perforation and root resorption, and root end filling, apexification and pulp capping applications.	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.
Intended population	Dental and Endodontic offices	Dental and Endodontic offices	Dental and Endodontic offices	Dental and Endodontic offices
Anatomical Site	Oral Cavity – root canal	Oral Cavity – root canal	Oral Cavity – root canal	Oral Cavity – root canal
Composition (bold text added to highlight similarities in composition between subject device and predicate / reference devices)	**Cementing agents, Radiopacifier, Calcium sodium phosphosilicate, Calcium Sulfate,** Tricalcium Phosphate, **Thickening agent, Filler, Carrier**	Tantalite **Tricalcium Silicate Calcium Aluminate Dicalcium Silicate Tricalcium aluminate Calcium Sulfate, Thickening agent Filler, Carrier**	**Tricalcium silicate Dicalcium silicate Calcium phosphate monobasic Zirconium oxide** Tantalum Pentoxide **Filler, Carrier**	**Calcium aluminates, Radiopacifier, Calcium sodium phosphosilicate, Thickening agent, Accelerator, Filler, Carrier**

Principle of operation	Vista BC Putty is an insoluble, radiopaque, hydraulic cement material that absorbs the moisture already present in the surrounding tissues of the root canal to set and solidify.	The MTA 2.3 ROOT & PUMP MATERIALS (design 2) is placed in the space created by the procedure and set *in vivo*. The mechanism of action is setting of the inorganic, ceramic cement in the presence of the water-based body fluids present in teeth.	iRoot FS is an insoluble, radiopaque and aluminum free material based on a calcium silicate composition, which requires the presence of water to set and harden.	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.
Indications for use	Repair of Root Perforation Repair of Root Resorption Root End Filling Apexification Pulp Capping	Repair of Root Perforation Repair of Root Resorption Root End Filling Apexification Pulp Capping	Repair of Root Perforation Repair of Root Resorption Root End Filling Apexification Pulp Capping	Permanent obturation of the root canal following root canal treatment.
Delivery form	Single paste	Single paste	Single paste	Single paste
Design	Pre-loaded syringe	Pre-loaded syringe	Pre-loaded syringe	Pre-loaded syringe, Disposable Intra Canal Tips
Nature of Contact (ISO 7405:2018)	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)	Category: External communicating device Contact: Tissue, bone and dentin Contact Duration: C - Permanent (>30 days)
Set Time	≤ 90 minutes	< 240 minutes	20 minutes	≤ 90 minutes
Sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Shelf Life	2 years	3 years	2 years	2 years
Rx / OTC	Rx Only	Rx Only	Rx Only	Rx Only
Standards	ISO 7405:2018 ISO 10993-1:2018 ISO 10993-5:2009 ISO 14971:2019 ISO 15223-1:2021	Unknown	Unknown	ISO 7405:2018 ISO 10993-1:2018 ISO 10993-5:2009 ISO 14971:2019 ISO 15223-1:2021

	ISO 11014:2009 ISO 20417:2021 ISO 6876:2001			ISO 11014:2009 ISO 20417:2021 ISO 6876:2001

Similarities between the subject device (Vista BC Putty) and the predicate device (MTA 2.3 (Design 2)) as well as reference device #1 (iRoot FS) and reference device #2 (Vista BC Sealer).

- Vista BC Putty has identical indications for use as its predicate device (MTA 2.3 (Design 2)).
- Vista BC Putty is classified under product code KIF, with respect to 21 CFR 872.3820 and the common name "Root canal filling material", which is identical to that of the predicate device (MTA 2.3 (Design 2)) and reference devices.
- Vista BC Putty has identical intended population use as the predicate device (MTA 2.3 (Design 2)) and reference devices and is used in the same anatomical location.
- Identical to the predicate device (MTA 2.3 (Design 2)) and reference devices, Vista BC Putty is a single component product.
- Vista BC Putty uses an identical mechanism of action for its indications compared to the predicate device (MTA 2.3 (Design 2)) and the reference devices, namely, all materials utilize water naturally present in the root canal / tooth to set and harden via cementation reactions.
- Identical to the predicate device (MTA 2.3 (Design 2)) and the reference devices, Vista BC Putty is classified as an external communicating device for permanent (>30 days) contact per ISO 7405:2018.
- Vista BC Putty composition consists of similar ingredients to the predicate device (MTA 2.3 (Design 2)) and reference devices. In fact, Vista BC Putty consists of all the same ingredients at slightly different ratios, except an accelerator, as reference device #2 (Vista BC Sealer). A further detailed explanation is provided within the 510(k) Section 12 – Substantial Equivalence Discussion.
    - The differences in composition do not raise any concerns as biocompatibility testing confirms the product is biocompatible for its intended use.
- Vista BC Putty's shelf life of two years is similar to the predicate device (MTA 2.3 (Design 2)) and identical to the reference devices.
- Identical to the predicate device (MTA 2.3 (Design 2)) and reference devices, Vista BC Putty is a non-aqueous paste-like material that is commercialized non-sterile.
- Identical to the predicate device (MTA 2.3 (Design 2)) and reference devices, Vista BC Putty is for prescription use (Rx) only.

Vista BC Putty shares similar intended use, technical characteristics, and composition to the predicate and reference devices. Therefore, Vista BC Putty is substantially equivalent to the predicate device and poses no additional safety or efficacy risks.

Discussion of Differences between the subject device (Vista BC Putty) and the predicate device (MTA 2.3 (Design 2)) as well as reference device #1 (iRoot FS) and reference device #2 (Vista BC Sealer).

- The formulation of Vista BC Putty is different than the predicate device (MTA 2.3 (Design 2)) and reference device (MTA 2.3 (Design 2)).
    - A further detailed explanation is provided within the 510(k) Section 12 – Substantial Equivalence Discussion. However, the differences in composition do not raise any concerns as biocompatibility testing confirms the product is biocompatible for its intended use.
    - Additionally, Vista BC Putty consists of all the same ingredients at slightly different ratios, except an accelerator, as reference device #2 (Vista BC Sealer).
    - Therefore, the subject device remains substantially equivalent to its predicate device.
- Vista BC Putty has a shorter set time compared to the predicate device (MTA 2.3 (Design 2)).
    - This does not raise any concerns as both materials set on the order of tens to hundreds of minutes and permanently remains within the root canal. Additionally, both reference devices have similar set times, too.
    - Therefore, the subject device remains substantially equivalent to its predicate device.

Applicable Standards

- ISO 7405:2018 – Dentistry – Evaluation of Biocompatibility of Medical Devices Used in Dentistry
- ISO 10993-1:2018 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
- 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 15233-1:2021 – Symbols to be used with Information to be Supplied by the Manufacturer – Part 1: General Requirements
- ISO 11014:2009 – Safety Data Sheet for Chemical Products
- ISO 20417:2021 – Information to be Supplied by the Manufacturer
- ISO 6876:2001 – Dental Root Canal Sealing Materials

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 Putty to MTA 2.3 (Design 2):

- ISO 6876 Testing
    - Benchtop testing on Vista BC Putty was completed following ISO 6876 test protocols for set time, film thickness, solubility and disintegration, and radiopacity. Vista BC Putty was compared to the predicate device (MTA 2.3 (Design 2)) and reference device

#1 (iRoot FS). Testing confirmed the substantial equivalence of the subject device to the predicate device.

- Shelf-Life Testing
  - Through accelerated shelf-life testing, Vista BC Putty was found to have a shelf-life of two years. Real time aging is being performed on Vista BC Putty to support shelf life during typical storage conditions.
- 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 Putty exhibits antimicrobial 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 Putty was found to yield better cytotoxicity results compared to the reference device, Vista BC Sealer.

8. Clinical Performance Testing and Compliance

Clinical performance is not deemed necessary.

9. Conclusion

Vista BC Putty is to be marketed by Inter-Med, Inc., 2200 South St., Racine, WI 53404, and is substantially equivalent to MTA 2.3 (Design 2) (K181917). The subject medical device has 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 Putty is substantially equivalent to the predicate device, MTA 2.3 (Design 2), and the product is safe and effective for its intended use.