January 8, 2025

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

Re: K241489
Trade/Device Name: ReminGel
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH
Dated: December 9, 2024
Received: December 9, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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Respiratory, ENT, and Dental Devices
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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)*

K241489

Device Name

ReminGel

Indications for Use *(Describe)*

To relieve dental hypersensitivity caused by bleaching procedures, cold, heat, acids, or sweets.

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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510(k) Summary
for
K241489 – ReminGel

1. Applicant

Submitter's Name: Alex Johnson
Khongchee Xiong

Date Summary Prepared: December 16, 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

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2. Device Name

Proprietary Name: ReminGel
Common Name: Varnish, Cavity
Classification Name: Cavity Varnish
Product Code: LBH
Device Class: Class 2

3. Predicate Device

Primary Predicate Device Super Seal (K120109) by Phoenix Dental Inc.

- Common Name: Varnish, Cavity
- Classification Name: Cavity Varnish
- Product Code: LBH
- Device Class: Class 2

Reference Device Senzzzzz Away (K120176) by Centrix, Inc.

- Common Name: Varnish, Cavity
- Classification Name: Cavity Varnish
- Product Code: LBH
- Device Class: Class 2

4. Device Description

ReminGel is a convenient, premixed, ready-to-use, opaque aqueous-based gel. ReminGel consists of suspended hydroxyapatite and calcium and phosphate salts that help restore a tooth's hydroxyapatite structure through remineralization. This remineralization results in tubule occlusion and blocks fluid flow in dentinal tubules, thereby relieving dentinal sensitivity. Additionally, ReminGel blocks nerve excitability through potassium release.

ReminGel is packaged in a 3oz (90mL) tube. ReminGel is for prescription use (Rx) and over-the-counter (OTC) use. ReminGel can be applied to teeth using dental appliances (e.g. fluoride tray, whitening tray, periotray, etc.) or via a toothbrush.

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

5. Intended Use / Indication for Use

- To relieve dental hypersensitivity caused by bleaching procedures, cold, heat, acids, or sweets.

6. Technological Characteristics and Substantial Equivalence

Characteristics	Proposed Device	Predicate Device	Reference Device
Trade Name	ReminGel	Super Seal	Senzzzzz Away Or D/Sense Crystal
Common name	Varnish, Cavity	Varnish, Cavity	Varnish, Cavity
Classification name	Cavity Varnish	Cavity Varnish	Cavity Varnish
Manufacturer	Inter-Med, Inc. / Vista Apex	Phoenix Dental Inc.	Centrix, Inc.
510(K) number	K241489	K120109	K120176
Product code	LBH	LBH	LBH
Device Description	ReminGel is a convenient, premixed, ready-to-use, opaque aqueous-based gel. ReminGel consists of	Super Seal Tooth Desensitizer is applied with an applicator by the use to aid in dentinal	Senzzzzz Away is an oxalate tooth desensitizing agent intended for over-the-counter-use. The

Characteristics	Proposed Device	Predicate Device	Reference Device
	suspended hydroxyapatite and calcium and phosphate salts that help restore a tooth's hydroxyapatite structure through remineralization. This remineralization results in tubule occlusion and blocks fluid flow in dentinal tubules, thereby relieving dentinal sensitivity. Additionally, ReminGel blocks nerve excitability through potassium release.	sensitivity. It contains an organic salt that reacts with calcium hydroxyapatite in the dentinal tubules. The formation of these calcium oxalate crystals inhibits and blocks fluid flow in the tubules, thereby relieving dentinal sensitivity.	combination of tubule occlusion and reduction in nerve excitability shown with oxalate formulations is responsible for the reduction in dentinal hypersensitivity to cold, hot and sweets. Senzzzzz Away is a one-part, opaque gel for single use.
Indication for use / intended use	To relieve dental hypersensitivity caused by bleaching procedures, cold, heat, acids, or sweets.	To aid in the relief from dentinal sensitivity caused by cold, heat, acids, sweets, or as the result from dental whitening agents.	To relieve dental hypersensitivity.
Packaging	ReminGel is packaged in a 3oz (90mL) tube. The tube of ReminGel is placed into a printed cardboard bearing instructions for use and appropriate labeling.	Super Seal is packaged in plastic bottles containing 8 mL with instructions for use.	Senzzzzz Away is packaged in one multi-use vial with two reusable brushes.
Years on the Market	-	12 years	12 years
Intended Population	Patients with dentinal sensitivity	Patients with dentinal sensitivity	Patients with dentinal sensitivity
Delivery Form	ReminGel can be applied to teeth using dental appliances (e.g. fluoride tray, whitening tray, periotray, etc.) or via a toothbrush.	Product placed direct onto affected area using cotton pellet or microsponge.	Product placed direct onto affected area
Mechanism of Action / Principle of Operation	Tubule occlusion	Tubule occlusion	Tubule occlusion
	Physical occlusion of dentinal tubules by forming hydroxyapatite. Additionally, ReminGel blocks nerve excitability through potassium release.	Physical occlusion of dentinal tubules by forming oxalate precipitates and block neural transmission through potassium ion release.	Physical occlusion of dentinal tubules by forming oxalate precipitates and block neural transmission through potassium ion release.
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity
Application Time	3-15 minutes	5 seconds	20 seconds

Characteristics	Proposed Device	Predicate Device	Reference Device
Nature of Body Contact (ISO 7405:2018)	External communicating device with permanent contact with tissue/bone/dentin	External communicating device with permanent contact with tissue/bone/dentin	External communicating device with permanent contact with tissue/bone/dentin
Composition (bold text added to highlight similarities in composition between subject device and predicate / reference devices)	**Potassium Salt,** Calcium Salt, Phosphate Salts, Buffering Agents, pH Modifier, Sweetener, **Thickener**, Flavoring, **Water**	**Water**, Oxalic Acid, **Potassium Salt Dihydrate**	Water, **Potassium Binoxalate**, Nitric Acid, and **Carbopol**
Sterility	Non-sterile	Non-sterile	Non-sterile
Shelf-Life	2 years	2 years	2 years
Rx / OTC	Rx and OTC	Rx	Rx and OTC
Standards	ISO 7405:2018 ISO 10993-1:2018 ISO 10993-5:2009 ISO 10993-10:2021 ISO 10993-23:2021 ISO 14971:2019 ISO 15223-1:2021 ISO 11014:2009 ISO 20417:2021	Unknown	Unknown

Similarities between the subject device (ReminGel) and the predicate and reference device (Super Seal and Senzzz Away, respectively).

- ReminGel has nearly identical indications for use as its predicate device (Super Seal); the only differences are nuanced descriptions for “bleaching” versus “whitening”.
- ReminGel is classified under product code LBH, with respect to 21 CFR 872.3260 and the common name “Cavity Varnish”, which is identical to that of the predicate device (Super Seal) and reference device (Senzzz Away).
- ReminGel has identical intended population use as the predicate device (Super Seal) and reference device (Senzzz Away) and is used in the same anatomical location.
- Identical to the predicate device (Super Seal) and reference device (Senzzz Away), ReminGel is a single component product.
- ReminGel uses a similar mechanism of action to relieve dental hypersensitivity (i.e. dentinal occlusion) compared to the predicate device (Super Seal) and the reference device (Senzzz Away).

    - The minor difference in mechanism of action between the use of hydroxyapatite formation and oxalate precipitate does not raise concern and the subject device remains substantially equivalent.
- ReminGel has an application time which is similar to the predicate device (Super Seal) and reference device (Senzzz Away). Because ReminGel helps remineralize dentin with its constituents, the nature of body contact classification is external communicating device with permanent contact with tissue/bone/dentin, which is equivalent to the predicate device (Super Seal) and reference device (Senzzz Away).
    - The minor difference in application time between minutes and seconds does not raise concern since the precipitate formation is slightly different and ReminGel has been deemed safe and effective for its intended use.
- ReminGel composition contains a potassium salt which is identical to the predicate device (Super Seal) and reference device (Senzzz Away).
    - The difference in composition such as other ionic salts, sweetener, flavoring, and thickeners do not raise concern since the precipitate formation is slightly different and biocompatibility testing confirms the product is biocompatible for its intended use.
- ReminGel's shelf life of two years is identical to the predicate device (Super Seal) and reference device (Senzzz Away).
- Identical to the predicate device (Super Seal) and reference device (Senzzz Away), ReminGel is an aqueous-based material and is commercialized non-sterile.
- Identical to the reference device (Senzzz Away), ReminGel is for prescription use (Rx) and over-the-counter use (OTC).

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

<u>Discussion of Differences between the subject device (ReminGel) and the predicate and reference device (Super Seal and Senzzz Away, respectively)</u>

- The formulation of ReminGel is different than the predicate device (Super Seal) and reference device (Senzzz Away). Specifically, ReminGel contains other ingredients (salts, buffering agents, pH modifier, sweetener, flavoring) that are not explicitly present in the predicate device or reference device.
    - The difference in composition such as other ionic salts, sweetener, flavoring, and thickeners do not raise concern since the precipitate formation is slightly different and biocompatibility testing confirms the product is biocompatible for its intended use. Additionally, the sweetener and flavoring is added for user satisfaction.
    - Therefore, the subject device remains substantially equivalent to its predicate device.
- ReminGel is applied using dental appliances (e.g. fluoride tray, whitening tray, periotray, etc.) or via a toothbrush, whereas the predicate device (Super Seal) is applied directly to the affected area

using a cotton pellet or microsponge and the reference device (Senzzz Away) is applied directly to the affected area.
    - This difference does not raise any significant concerns as the ReminGel was confirmed to be biocompatible as the device passed relevant tests within ISO 7405:2018.
    - Therefore, the subject device remains substantially equivalent to its predicate device.
- ReminGel is packaged in a plastic 3oz (90mL) tube as compared to an 8mL bottle (predicate device, Super Seal) or multi-use vial (reference device, Senzzz Away).
    - This difference does not raise any significant concerns as it is simply a volume difference offered to users. Additionally, the medical devices are applied in slightly different techniques resulting in different package volumes.
- ReminGel is for prescription use (Rx) and over-the-counter use (OTC), whereas the predicate device (Super Seal) is for prescription use (Rx) only.
    - Reference is made to the reference device (Senzzz Away) which is for prescription use (Rx) and over-the-counter use (OTC) and bears many similarities to the subject device as discussed in the previous section.

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 10993-10:2021 – Biological Evaluation of Medical Devices – Part 10: Tests for Skin Sensitization
- ISO 10993-23:2021 – Biological Evaluation of Medical Devices – Part 23: Tests for Irritation
- 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

7. Non-Clinical Performance Testing and Compliance

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

- Tubule Occlusion Testing
    - An *in vitro* tubule occlusion study was performed on resected human teeth using ReminGel and Super Seal. Identical to the predicate device (Super Seal), ReminGel

visibly occluded dentinal tubules demonstrating that the product will inhibit dentin sensitivity.

- Shelf-Life Testing
  - Through accelerated shelf life testing, ReminGel was found to have a shelf-life of two years. Real time aging is being performed on ReminGel 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.
- Cytotoxicity Testing
  - ReminGel was found to yield better cytotoxicity results compared to the predicate device, SuperSeal.
- Irritation Testing
  - ReminGel was found to be a non-irritant.
- Sensitization Testing
  - ReminGel was found to be a non-sensitizing agent.

8. Clinical Performance Testing and Compliance

Clinical performance is not deemed necessary.

9. Conclusion

ReminGel is to be marketed by Inter-Med, Inc., 2200 South St., Racine, WI 53404, and is substantially equivalent to Super Seal (K120109). 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 ReminGel is substantially equivalent to the predicate device, Super Seal, and the product is safe and effective for its intended use.