March 18, 2026

Sangi Co., Ltd.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
7 Giralda Farms, Suite 120a
Madison, New Jersey 07940

Re: K260830
Trade/Device Name: APAPRO Desensitizer Homecare (Remineralizing Anti-sensitivity Toothpaste)
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity varnish
Regulatory Class: Class II
Product Code: LBH
Dated: March 13, 2026
Received: March 13, 2026

Dear Dave Yungvirt:

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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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)*
K260830

Device Name
APAPRO Desensitizer Homecare

Indications for Use *(Describe)*
APAPRO Desensitizer Homecare is a fluoride-free daily-use cleaning toothpaste that also provides relief from tooth sensitivity due to cold, heat, acids, sweets or contact, through its action of occluding dentin tubules through surface coating, promoting an environment conducive to remineralization.

Intended Population: For use in Adult and Pediatric Population

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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APAPRO Desensitizer Homecare

K260830

Submitter Information:

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Preparation Date: 18 Mar 2026

1. Device Nomenclature:

Trade Name: APAPRO Desensitizer Homecare

Common Name: Remineralizing Anti-sensitivity Toothpaste

Classification Name: Cavity Varnish (21 CFR 872.326 Product code LBH)

2. Legally Marketed Predicate Device:

Device Name: APAPRO Desensitizer

510(k) Number: (K220419)

Applicant: Sangi Co., Ltd.

3. Legally Marketed Reference Device:

Device Name: Oralief OTC Toothpaste for Sensitive Teeth

510(k) Number: (K080228)

Applicant: Novamin Technology, Inc.

4. Device Description:

APAPRO Desensitizer Homecare is a fluoride-free daily-use toothpaste device that contains hydroxyapatite, the main component of teeth, as its active ingredient. The

formulation is designed to clean teeth as well as to help restore a tooth's hydroxyapatite structure through surface coating, promoting an environment conducive to remineralization, which results in physical occlusion of exposed dentin tubules, providing relief from tooth hypersensitivity. The hydroxyapatite deposited into the dentin tubules by APAPRO Desensitizer Homecare acts as a template for the further deposition of large amounts of calcium and phosphate ions, promoting crystal integrity and growth.

5. Indication/ Intended Use:

APAPRO Desensitizer Homecare is a fluoride-free daily-use cleaning toothpaste that also provides relief from tooth sensitivity due to cold, heat, acids, sweets or contact, through its action of occluding dentin tubules through surface coating, promoting an environment conducive to remineralization.

6. Technological Comparison:

• Mechanism of Action: Both the subject (APAPRO Desensitizer Homecare) and the predicate (APAPRO Desensitizer) depend on deposition of hydroxyapatite to occlude dentinal tubules.

• Concentration: APAPRO Desensitizer Homecare uses a somewhat lower concentration of hydroxyapatite, but the mechanism remains the same.

• Usage Context: APAPRO Desensitizer Homecare is designed for repeated, everyday OTC use with a toothbrush; the predicate is for professional in-office application using rubber cup or cotton swab. This difference is reflected to some extent in the formulation but there is no difference in the fundamental technology.

7. Safety and Performance Data:

The ability of APAPRO Desensitizer Homecare to reduce tooth hypersensitivity was evaluated through non-clinical testing. The mechanism of action is based on restoration of the tooth's hydroxyapatite structure through surface coating, promoting an environment conducive to remineralization, resulting in occlusion of exposed dentin tubules.

Non-clinical testing demonstrated that APAPRO Desensitizer Homecare physically occludes exposed dentin tubules. Scanning electron microscopy (SEM) micrographs of dentin samples treated with APAPRO Desensitizer Homecare were compared with those treated with the predicate device, APAPRO Desensitizer. Both products demonstrated comparable dentin tubule occlusion, primarily through deposition of a hydroxyapatite layer on the dentin surface.

Quantitative dentinal tubule occlusion testing showed an average occlusion rate of 93.1% for APAPRO Desensitizer Homecare. In comparison, the predicate device demonstrated an average dentin tubule occlusion rate of 91.5% when applied using a rubber cup and 93.2% when applied using a cotton swab. These results indicate that APAPRO Desensitizer Homecare performs comparably to the predicate device with respect to dentin tubule occlusion.

The relative abrasivity of APAPRO Desensitizer Homecare was evaluated at the Indiana University School of Dentistry using the American Dental Association (ADA) recommended procedure for determination of toothpaste abrasivity. The product demonstrated a mean Radioactive Dentin Abrasion (RDA) value of 23.42 ± 0.59. This RDA value is well below the generally accepted safety threshold for daily use (RDA < 250), indicating that APAPRO Desensitizer Homecare is safe for routine oral care use.

8. Device Comparison Table:

Descriptive Information	Subject Device: APAPRO Desensitizer Homecare	Predicate Device: APAPRO Desensitizer (K220419)	Reference Device: Oralief OTC Toothpaste for Sensitive Teeth (K080228)	Differences
Classification Name	Cavity Varnish	Cavity Varnish	Cavity Varnish	Same
Regulatory Class	Class II	Class II	Class II	Same
Product Code	LBH	LBH	LBH	Same
Device Description	APAPRO Desensitizer Homecare is a fluoride-free daily-use toothpaste device that contains hydroxyapatite, the main component of teeth, as its active ingredient. The formulation is designed to clean teeth as well as to help restore a tooth's hydroxyapatite structure through surface coating, promoting an environment conducive to remineralization, which results in physical occlusion of exposed dentin tubules, providing relief from tooth hypersensitivity. The hydroxyapatite deposited into the dentin tubules by APAPRO Desensitizer Homecare acts as a template for the further deposition of large amounts of calcium and phosphate ions, promoting crystal integrity and growth.	APAPRO Desensitizer is a fluoride-free tooth desensitizing paste that utilizes hydroxyapatite, the main component of teeth, as its active ingredient to relieve tooth sensitivity by physically occluding exposed dentin tubules. The hydroxyapatite deposited into dentin tubules by APAPRO Desensitizer then acts as a template for the further deposition of large amounts of calcium and phosphate ions, promoting crystal integrity and growth.	Oralief™ OTC Toothpaste for Sensitive Teeth is a daily-use, fluoride-free toothpaste device that incorporates NovaMin® (calcium sodium phosphosilicate) as its active ingredient. The non-aqueous formulation is designed to clean teeth as well as to physically occlude dentin tubules for the reduction of tooth sensitivity. When exposed to an aqueous environment, NovaMin® undergoes a rapid surface reaction, allowing it to physically occlude tubules. Within a short period of time, essentially all of the NovaMin reacts to form hydroxycarbonate apatite (HCA), which is chemically and structurally similar to natural tooth mineral.	Similar / Similar
Indication/ Intended Use	APAPRO Desensitizer Homecare is a fluoride-free daily-use toothpaste that also provides relief from tooth sensitivity due to cold, heat, acids, sweets or contact, through its action of occluding dentin tubules through surface coating, promoting an environment conducive to remineralization.	APAPRO Desensitizer is a fluoride-free paste that is indicated to provide relief from tooth hypersensitivity resulting from cold, heat, acids, sweets, or contact, through its action of dentin tubule occlusion.	Oralief OTC Toothpaste for Sensitive Teeth is a fluoride-free daily use cleaning toothpaste that also provides rapid and continual relief from tooth sensitivity due to cold, heat, acids, sweets or contact, through its action of the occlusion of dentin tubules.	Similar / Similar

Descriptive Information	Subject Device: APAPRO Desensitizer Homecare	Predicate Device: APAPRO Desensitizer (K220419)	Reference Device: Oralief OTC Toothpaste for Sensitive Teeth (K080228)	Differences
Packaging	4.23oz (120g) aluminum-laminate tube. The tube is enclosed in an individual paperboard box and placed in a cardboard carton for shipment.	1.94oz (55g) aluminum-laminate tube. The tube is enclosed in an individual paperboard box, which is then shrink-wrapped in PE, and placed in a cardboard carton for shipment.	Not disclosed	Different
Intended Population	For use in Adult and Pediatric Population	For use in Adult Population	Not disclosed	Different
Delivery Form	Daily-use over-the-counter toothpaste for application with a toothbrush.	Applied with a cotton bud or swab, in a customized dental tray, or using a rubber cup attached to a dental handpiece at low (>1000 rpm) revolution speed.	Daily-use over-the-counter toothpaste for application with a toothbrush.	Similar / Same
Mode of Action	APAPRO Desensitizer Homecare directly occludes dentin tubules by depositing a crystalline layer of synthetic hydroxyapatite directly onto the tooth surface, promoting an environment conducive to remineralization, which physically occludes exposed dentin tubules, resulting in desensitization.	APAPRO Desensitizer directly occludes dentin tubules by depositing a crystalline calcium phosphate layer, i.e. introducing synthetic hydroxyapatite directly onto the tooth surface, resulting in the physical occlusion of exposed dentin tubules, which results in desensitization	Calcium phosphosilicate particles react with the user's saliva in an aqueous environment to release calcium and phosphate ions, which forms a layer of hydroxycarbonate apatite (calcium phosphate) over time. The calcium phosphate layer physically occludes exposed dentinal tubules and blocks hydrodynamic flow to achieve the desensitization effect.	Same / Similar
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity	Same
Application Time	Twice per day: 2 minutes brushing, spit out, light rinse (or no rinse)	Single application: 30 seconds per tooth	Daily frequency not disclosed	Same
Nature of Body Contact	Long term (>30 days)	Limited (<24 hours)	Long term (>30 days)	Different / Same
Composition	Calcium phosphate (Hydroxyapatite) + Inactive Ingredients	Calcium phosphate (Hydroxyapatite) + Inactive Ingredients	NovaMin® (calcium sodium phosphosilicate) + Inactive Ingredients	Same / Similar
Biocompatibility	Biocompatible, non-antigenic	Biocompatible, non-antigenic	Biocompatible, non-antigenic	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
Shelf-life	3 years	3 years	Not disclosed	Same
Prescription / OTC	OTC	Prescription	OTC	Different / Same

9. Biocompatibility:

Biocompatibility testing in accordance with ISO 10993 was previously performed on APAPRO Desensitizer, the predicate device. The formulation of APAPRO Desensitizer Homecare is similar to that of the predicate device, with the addition of certain ingredients that are commonly used in commercially marketed toothpaste products.

Based on the similarity in formulation, the established history of safe use of the additional ingredients, and the biocompatibility data available for the predicate device, no additional biocompatibility testing was conducted for APAPRO Desensitizer Homecare. A biocompatibility justification, including the predicate device test reports and rationale for not performing additional testing on the added ingredients, has been provided in the 510(k) submission.

Based on this information, APAPRO Desensitizer Homecare is considered biocompatible and does not pose an unacceptable biological risk to users when used as intended in both adult and pediatric populations.

10. Conclusion:

APAPRO Desensitizer Homecare is considered substantially equivalent to the legally marketed predicate device, APAPRO Desensitizer. Both products are indicated for the relief of tooth hypersensitivity through the formation of a calcium hydroxyapatite layer on the tooth surface, promoting an environment conducive to remineralization, which physically occludes dentin tubules.

Additionally, both products have demonstrated comparable effectiveness in dentin tubule occlusion. No additional safety concerns were identified when comparing APAPRO Desensitizer Homecare to APAPRO Desensitizer.