February 16, 2022

Sangi Co, Ltd
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K220419
Trade/Device Name: Apapro Desensitizer
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity varnish
Regulatory Class: Class II
Product Code: LBH
Dated: February 7, 2022
Received: February 14, 2022

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 (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, 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)*
K220419

Device Name
APAPRO Desensitizer

Indications for Use *(Describe)*
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.

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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Sangi Co., Ltd.
Traditional 510(k)
APAPRO Desensitizer

K220419

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Contact Person:	Douglas Mercadante
Preparation Date:	12 May 2021

1. Device Nomenclature:

Trade Name:	APAPRO Desensitizer
Common Name:	Tooth Desensitizing Paste
Classification Name:	Cavity Varnish (21 CFR 872.326 Product code LBH)

2. Legally Marketed Predicate Device:

Device Name:	Oralief™ Therapy for Sensitive Teeth
510(k) Number:	K040858
Applicant:	NovaMin Technology, Inc.

3. Device Description:

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.

4. Indications for Use

   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.

5. Intended Use

   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. APAPRO Desensitizer is intended to be prescribed and applied by dental physicians for use in the Adult Population.

6. Technological Characteristics:

   Both APAPRO Desensitizer and the selected predicate device Oralief™ Therapy for Sensitive Teeth are intended to be used to treat the same disorder, namely for the relief of tooth hypersensitivity, by the same mode of action, which is the deposition of a calcium hydroxyapatite layer onto the tooth surface resulting in the physical occlusion of dentin tubules. The two devices differ in that Oralief™ Therapy for Sensitive Teeth uses calcium sodium phosphosilicate (NovaMin®) as its active ingredient, which when introduced to the physiological fluid of the mouth, reacts to form a hydroxycarbonate apatite layer on the teeth, whereas APAPRO Desensitizer introduces synthetic hydroxyapatite directly onto the tooth surface. APAPRO Desensitizer is to be prescribed and applied by a dental professional. Oralief™ Therapy for Sensitive Teeth is also a home-use device to be prescribed by dental professionals.

7. Safety and Performance Data:

   The ability of APAPRO Desensitizer to provide relief from tooth hypersensitivity was shown by non-clinical tests demonstrating that it physically occludes exposed dentin tubules. The SEM micrographs of dentin samples with tubules occluded by APAPRO Desensitizer were compared to SEM Micrographs of NovaMin-treated dentin samples. The SEM Micrographs of APAPRO Desensitizer and NovaMin-treated samples showed similar occlusion of the dentin tubules, which was achieved in both cases by the deposition of a hydroxyapatite layer onto the surface of the tooth. Thus APAPRO Desensitizer was shown to be as effective as the NovaMin® found in the predicate device in occluding dentin tubules.

8. Device Comparison Table:

Trait	**APAPRO Desensitizer New Device**	**Oralief™ Therapy for Sensitive Teeth Predicate Device**	**Equivalence Determination**
510(k) Number	TBD	K040858	N/A
Classification Number	872.3260	872.3260	Equivalent
Product Code	LBH	LBH	Equivalent
Product Classification	Class II	Class II	Equivalent

Prescription/ Over-the-counter use	Prescription	Prescription	Equivalent
Intended Use	For dental hypersensitivity relief	For dental hypersensitivity relief	Equivalent
Indications for Use	Provides rapid and continual relief from tooth hypersensitivity due to cold, heat, acids, sweets, or contact through its action of the occlusion of dentin tubules.	Provides rapid and continual relief from tooth hypersensitivity due to cold, heat, acids, sweets, or contact through its action of the occlusion of dentin tubules.	Equivalent
Active Ingredient	20% w/w Calcium Phosphate (Hydroxyapatite)	7.5% w/w Calcium Sodium Phosphosilicate (NovaMin®)	Equivalent*
Device Action	APAPRO Desensitizer directly occludes dentin tubules by depositing a crystalline calcium phosphate layer on the tooth surface (i.e. hydroxyapatite).	The NovaMin® particles react with the user's saliva to release calcium and phosphate ions, which precipitate onto the tooth surface as a crystalline calcium phosphate layer (i.e. hydroxycarbonate apatite).	Equivalent
Material Produced to Occlude Tubules	Hydroxyapatite	Hydroxycarbonate Apatite	Equivalent*
Performance	The hydroxyapatite layer occludes exposed dentin tubules, which results in desensitization.	The hydroxycarbonate apatite layer occludes exposed dentin tubules, which results in desensitization.	Equivalent
Biocompatibility	Biocompatible, non-antigenic	Biocompatible, non-antigenic	Equivalent
Sterility	Supplied non-sterile	Supplied non-sterile	Equivalent

*Details are provided in Section 12

9. Biocompatibility

Biocompatibility tests in accordance with ISO 10993 have been performed on APAPRO Desensitizer. A biological risk assessment, captured in the enclosed Biological Evaluation Report, has also been performed and included in this Traditional 510(k) application package. The results of the biocompatibility assessment indicated that APAPRO Desensitizer has no hazardous effects to the consumer when used as directed in the Adult Population.

10. Conclusions:

APAPRO Desensitizer is considered to be substantially equivalent to the legally marketed predicate device, Oralief™ Therapy for Sensitive Teeth. Both products are indicated for the relief of tooth hypersensitivity through the occlusion of dentin tubules. Both products achieve this by producing a calcium hydroxyapatite layer on the tooth surface. Additionally, both products have been shown to have comparable effectiveness with regards to tubule occlusion. No additional safety concerns have been observed when comparing APAPRO Desensitizer to Oralief™ Therapy for Sensitive Teeth.