June 11, 2026

Nagy Oral Technology Qinhuangdao Co., Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801
No. 161 East Lu Jiazui Rd.Pudong
Shanghai, 200120
China

Re: K253052
Trade/Device Name: Fluoride Varnish (Type A,Type C)
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH
Dated: May 14, 2026
Received: May 14, 2026

Dear Boyle Wang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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.

510(k) Number *(if known)*
K253052

Device Name
Fluoride Varnish (Type A,Type C)

Indications for Use *(Describe)*
The Fluoride Varnish is indicated to relieve dental hypersensitivity.

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.

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510(k) Summary

K253052

This summary is submitted in accordance with 21 CFR 807.92.

1.0 Submission Sponsor

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Date of Preparation: June 11,2026

2.0 Device Information

Trade name: Fluoride Varnish
Common name: Fluoride Varnish
Classification name: Varnish, Cavity
Production code: LBH
Regulation number: 21 CFR 872.3260
Classification: Class II
Panel: Dental

3.0 Identification of Predicate Device and Reference Device

Predicate#

510(k) Number: K132109
Trade/Product Name: ENAMELAST
Manufacturer: ULTRADENT PRODUCTS INC. / ORATECH LLC

Reference#
510(k) Number: K222891
Trade/Product Name: Dental Desensitizer
Manufacturer: Guangzhou Beogene Biotech Co., Ltd.

4.0 Device Description

The subject device, Fluoride Varnish, is a flavored, xylitol-sweetened topical fluoride dental product supplied in liquid/paste form. It is applied to exposed dentin surfaces for the purpose of treatment dentinal hypersensitivity.
It is available in two types: Type A (5% Sodium Fluoride) and Type C (1.33% Sodium Fluoride). The device is delivered in either single-dose packages (aluminum foil pouch containing dental brush, and fluoride varnish) or multi-dose packages (type A: composite aluminum tube).type C (LDPE Bottle, tray and dental brush)

5.0 Indication for Use Statement

The Fluoride Varnish is indicated to relieve dental hypersensitivity.

6.0 Non-clinical Test Conclusion

Bench Testing:
- Physical and mechanical properties of the subject device were evaluated according to FDA-recognized version ISO 17730 Dentistry - Fluoride varnishes.

Performance testing including color, viscosity, density, PH, fluoride release, fluoride contents and dentinal tubule occlusion.
The test results demonstrated the Subject device meets the property requirements of the referenced standards.

Biocompatibility Testing:
The Fluoride Varnish was assessed as a surface medical device in contact with mucosal membrane for less than or equal to 24 hours. The biocompatibility testing was performed according to FDA currently-recognized versions of biocompatibility consensus standards ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process and ISO 7405:2018 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry.
The following biological safety aspects have been addressed:
- Cytotoxicity – ISO 10993-5
- Sensitization – ISO 10993-10
- Irritation – ISO 10993-23
- Acute Systemic Toxicity- ISO 10993-11

Sterility and Shelf-Life Testing:
The device is provided non-sterile.
From the Shelf life testing, the subject Fluoride Varnish has a shelf life of 3 years.

7.0 Technological Characteristics and Substantial Equivalence

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 1- Comparison of Technology Characteristics

Item	Subject Device	Predicate Device	Reference Device	Remark
510(k) No.	K253052	K132109	K222891	
Product Name	Fluoride Varnish	Enamelast™	Dental Desensitizer	--
Product Code	LBH	LBH	LBH	Same
Regulation No.	21 CFR 872.3260	21 CFR 872.3260	21 CFR 872.3260	Same
Class	Class II	Class II	Class II	Same
Intended Use/ Indication for Use	The Fluoride Varnish is indicated to relieve dental hypersensitivity.	Enamelast™ Fluoride Varnish is 5% sodium fluoride in a varnish carrier which produces a mechanical occlusion of the dentinal tubules in the treatment of tooth hypersensitivity.	The Dental Desensitizer is a colorless transparent gel that is applied to the sensitive part of the tooth to form a film, sealing the exposed dentin tubules and relieving dentin allergy. The product is used either by a dental professional in the dental office or provided to the patient for home treatment of dentin sensitivity.	Same* All three devices are indicated for use in the treatment of hypersensitive teeth.
Prescription or OTC	Prescription Use	Prescription Use	Prescription Use	Same
Intended user	Dental professional	Dental professional	Dental professional	Same
Materials	Type A –5% sodium fluoride Resin based; Type C –1.33% sodium fluoride Resin based	5% sodium fluoride Resin based	3% Potassium Nitrate; 0.11% w/w Fluoride Ion 1200 ppm	Different Different questions of safety or effectiveness are not raised because significant concerns are not raised. The amount of fluoride ions between the subject and reference device is similar.
Amount of fluoride Ion	Type A: 22,500 ppm Type C: 6000 ppm	22,500 ppm		
Physical properties	Appearance: Light yellow; Odor: Fruit flavor State: Type A – paintable	Appearance: White resinous material Odor: Bubble gum or Mint PH: Mint -2.95	Appearance: Colorless, odourless, transparent gel, no visible impurity	Different The difference due to the different components.

	paste; Type C – paintable liquid PH:4-8 Shelf Life: 36 months	Shelf Life: 18 months	PH: 6-7.5 Shelf Life: 24 months	The essential design of these products is the same. All three products are formulated with a polymer that coats the teeth, a fluoride mineral, a solvent to dissolve the fluoride mineral, and additives such as flavoring agents and rheology modifiers. So different questions of safety or effectiveness are not raised.
Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Biocompatibility	Passed the tests as per ISO 10993-5, ISO 10993-10 and ISO 10993-11 (Cytotoxicity, sensitization, irritation, acute systemic toxicity)	Passed the tests as per ISO 10993-5(Cytotoxicity)	Passed the tests as per ISO 10993-5, ISO 10993-10 and ISO 10993-11 (Cytotoxicity, sensitization, irritation, acute systemic toxicity)	Same

8.0 Summary of Clinical Test

Clinical testing was not required for this submission.

9.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is substantially equivalent to the legally marketed predicated device.