May 27, 2025

Young Dental Manufacturing Co. 1, LLC
Brian Prange
Director, Product Development
13705 Shoreline Ct. East
Earth City, Missouri 63045

Re: K241041
Trade/Device Name: Silver Fluoride Hypersensitivity Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity varnish
Regulatory Class: Class II
Product Code: PHR

Dear Brian Prange:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on February 28, 2025. Specifically, FDA is updating this SE Letter due to a typo in the clearance date, which was incorrectly dated as February 28, 2005.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Michael Adjodha, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices, 301-796-6276, michael.adjodha@fda.hhs.gov.

Sincerely,

MICHAEL E. ADJODHA -S

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

February 28, 2005

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Brian Prange
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13705 Shoreline Ct. East
Earth City, Missouri 63045

Re: K241041
Trade/Device Name: Silver Fluoride Hypersensitivity Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: PHR
Dated: January 27, 2025
Received: January 27, 2025

Dear Brian Prange:

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
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)*

K241041

Device Name

Silver Fluoride Hypersensitivity Varnish

Indications for Use *(Describe)*

Young Silver Fluoride Hypersensitivity Varnish is indicated for the treatment of dental hypersensitivity in adults.

It is intended for professional use only.

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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510(k) Summary

K241041

Premarket Notification (510(k)) Number

Submitter's Name	Young Dental Manufacturing Co. 1, LLC 13705 Shoreline Ct. East Earth City, MO 63045 Telephone: (314) 344-0010
Contact Person	Brian Prange Director of Product Development Young Dental Manufacturing Co. 1, LLC 13705 Shoreline Ct. East Earth City, MO 63045
Establishment Registration Number	1941138
Date Prepared	February 28, 2025
Device Trade Name	Young Silver Fluoride Hypersensitivity Varnish
Device Common Name	Cavity Varnish
Classification Name	Cavity Varnish
Product Code	PHR
Device Classification	Class II
Panel	Dental
Regulatory Classification	21 CFR 872.3260
Type of 510(k) Submission	Traditional
Legally Marketed Predicate Device	Elevate Advantage Arrest (K102973)

Description

Young Silver Fluoride Hypersensitivity Varnish is a formulation of silver, sodium fluoride, chitosan, acetic acid, and purified water intended for the treatment of dental hypersensitivity in adults. It is intended for professional use only.

Like other 510(k) cleared dental hypersensitivity varnishes including the predicate device, the proposed device works by physically occluding dentinal tubules through its silver and fluoride components. It contains small silver particles to facilitate their entry into the dentinal tubules, as well as chitosan and acetic acid to evenly disperse the solution. The product is supplied in a 10mL bottle with a dropper dispensing tip.

One to two drops of the varnish can treat up to 8 sites. If needed, a second application of the varnish may be administered after 1 week.

Indications for Use

Young Silver Fluoride Hypersensitivity Varnish is indicated for the treatment of dental hypersensitivity in adults. It is intended for professional use only.

Predicate Device

Young Silver Fluoride Hypersensitivity Varnish is substantially equivalent to the Elevate Advantage Arrest Hypersensitivity Varnish cleared under K102973. Both devices are intended for the treatment of dental hypersensitivity in adults. Both the subject and predicate devices also have similar technological characteristics. In particular, both devices contain silver and fluoride to physically occlude dentinal tubules in the treatment of dental hypersensitivity.

Please refer to the Substantial Equivalence Summary Comparison Table below for a summary of the similarities and differences between the subject and predicate devices.

Description of Operation/Use

After cleaning the tooth/teeth to be treated and adjacent teeth with a non-fluoride prophylaxis paste and prophy cup, the condition of the teeth should be assessed. Only teeth with normal pulp status should be treated. The affected area of the tooth is isolated with cotton rolls and gingival tissue of the affected tooth is protected with petroleum jelly or similar. Alternatively, a rubber dam or saliva evacuator can be used to isolate the area.

One to two drops of solution (i.e., the subject device) can treat up to 8 sites per patient. The solution is dispensed from the device bottle's dropper tip into a disposable dappen dish. Ensuring that the affected tooth surface is dry, a small brush applicator is used to carefully transfer the solution directly to the affected tooth surface, which is allowed to air dry.

All protective/isolation materials used in the mouth are removed and the dappen dish and applicators are discarded in accordance with local regulations. If needed, a second application may be administered after 1 week.

Young Silver Fluoride Hypersensitivity Varnish is a prescription device intended for professional use only.

Technological Characteristics Summary

Young Silver Fluoride Hypersensitivity Varnish is substantially equivalent to Elevate Advantage Arrest (K102973) with respect to intended use, principle of operation/use, technological characteristics, and performance.

Both devices are cavity varnishes with the same intended use and the same key functional ingredients (silver and fluoride) that physically occlude dentinal tubules in the treatment of hypersensitivity. While the diamine (ammonia component) in the predicate device is used to allow the silver and fluoride to be in an evenly dispersed solution, the subject device uses acetic acid and chitosan to evenly disperse the solution. The subject device includes small silver particles to facilitate their entry into the dentinal tubules. These differences do not affect the overall means by which the silver and fluoride in the subject and predicate devices are used to occlude dentinal tubules in the treatment of dental hypersensitivity and do not raise new questions of safety or effectiveness.

Substantial Equivalence Summary Comparison Table

Characteristic	Young Silver Fluoride Hypersensitivity Varnish (Subject Device)	Elevate Advantage Arrest (K102973)	Comparison
Classification Name	Cavity Varnish	Cavity Varnish	Identical
CFR Citation	21 CFR 872.3260	21 CFR 872.3260	Identical
Classification Panel	Dental	Dental	Identical
Classification	Class II	Class II	Identical
Product Code	PHR	PHR	Identical

Characteristic	Young Silver Fluoride Hypersensitivity Varnish (Subject Device)	Elevate Advantage Arrest (K102973)	Comparison
Product Code Description	Diamine Silver Fluoride Dental Hypersensitivity Varnish	Diamine Silver Fluoride Dental Hypersensitivity Varnish	Although the proposed product does not include diamine silver, the diamine (ammonia component) in the predicate device is used to allow the silver and fluoride to be in an evenly dispersed solution, while the proposed device uses acetic acid and chitosan to evenly disperse the solution. Both devices contain silver and fluoride to physically occlude the dentinal tubules in the treatment of dental hypersensitivity, therefore these differences do not raise different questions of safety or effectiveness. Performance testing demonstrates the subject device occludes dentinal tubules and releases silver and fluoride ions comparably to the predicate device.
Active Ingredients	0.20% silver 3.00% sodium fluoride	38% silver diamine fluoride	Both formulations contain silver and

Characteristic	Young Silver Fluoride Hypersensitivity Varnish (Subject Device)	Elevate Advantage Arrest (K102973)	Comparison
			fluoride to achieve the intended effect of occluding dentinal tubules in the treatment of hypersensitivity. The subject product includes silver and fluoride, but not silver diamine fluoride (i.e., ammonia). Biocompatibility testing has been successfully completed for the subject device.
Device Description	Varnish containing silver and fluoride applied directly to affected tooth or teeth in the treatment of dental hypersensitivity.	Varnish containing silver and fluoride applied directly to affected tooth or teeth in the treatment of dental hypersensitivity.	Similar. Both devices have the same intended use and the same functional ingredients (silver and fluoride) to physically occlude dentinal tubules in the treatment of dental hypersensitivity. The subject device additionally includes chitosan and acetic acid to evenly disperse the solution and omits the diamine (ammonia) used in the predicate.

Characteristic	Young Silver Fluoride Hypersensitivity Varnish (Subject Device)	Elevate Advantage Arrest (K102973)	Comparison
			Both varnishes are used the same way in the treatment of dental hypersensitivity. Performance testing demonstrates the subject device occludes dentinal tubules and releases silver and fluoride ions comparably to the predicate device.
Intended Use/ Indications for Use	Treatment of dental hypersensitivity in adults	Treatment of dental hypersensitivity in adults	Identical
Technological Characteristics	Composition: • Colloidal silver and silver cation mixture • Sodium fluoride • Chitosan • Acetic acid • Purified water	Composition: • 38% silver diamine fluoride Note: beyond the public disclosure of 38% silver diamine fluoride, the exact formulation of Elevate Advantage Arrest is proprietary. In dentistry practice, silver diamine fluoride is commonly prepared by mixing powdered silver fluoride into an ammonia/water mixture as follows: 25% silver 8% ammonia	Similar. Both devices contain silver and fluoride to occlude dentinal tubules in the treatment of dental hypersensitivity. The proposed device contains small silver particles to facilitate their entry into the dentinal tubules as well as chitosan and acetic acid to evenly disperse the solution. These differences do not affect the overall means by which the dentinal tubules are occluded in the treatment of

Characteristic	Young Silver Fluoride Hypersensitivity Varnish (Subject Device)	Elevate Advantage Arrest (K102973)	Comparison
		5% fluoride 62% water	hypersensitivity nor do they raise new questions of safety and effectiveness. Performance testing demonstrates the subject device occludes dentinal tubules and releases silver and fluoride ions comparably to the predicate device.
pH	Acid	Strong Base	While the proposed product has an acid pH and the predicate is a strong base (ammonia), these differences do not affect safety or effectiveness. The ammonia in the predicate device is used to allow the silver and fluoride to be in an evenly dispersed solution, while the proposed device uses acetic acid and chitosan to evenly disperse the solution. In addition, the subject device is used no more frequently, and potentially less frequently, than the

Characteristic	Young Silver Fluoride Hypersensitivity Varnish (Subject Device)	Elevate Advantage Arrest (K102973)	Comparison
			predicate device, since the subject and predicate devices may both be applied once or twice, while the predicate device may additionally be applied a third time.
Mechanism of Action	Like other dental hypersensitivity devices, the formulation works by physically occluding dentinal tubules. Like other silver fluoride formulations cleared under the 510(k) process, treatment of dental hypersensitivity is achieved by the silver and fluoride components of the formulation, which physically plug or close exposed dentinal tubules.	Like other dental hypersensitivity devices, the formulation works by physically occluding dentinal tubules. Like other silver fluoride formulations cleared under the 510(k) process, treatment of dental hypersensitivity is achieved by the silver and fluoride components of the formulation, which physically plug or close exposed dentinal tubules.	Similar – both devices include silver and fluoride and treat dental hypersensitivity by physically occluding dentinal tubules. Performance testing demonstrates the subject device occludes dentinal tubules and releases silver and fluoride ions comparably to the predicate device.
Number of Application Steps	1-step	1-step	Same
Method of Application	One drop treats up to 8 sites	One drop treats 5 sites	Similar
Number of Applications	Up to two	Up to three	Similar. Subject device has lower maximum frequency of use.

Performance Testing

As described below, comprehensive bench and biocompatibility was submitted to confirm product conformance with device requirements and substantially equivalent performance as the predicate device. Performance data demonstrated dentinal occlusion and silver and fluoride ion release were comparable to the predicate device. Additional testing included transportation, stability/shelf life, device lifetime testing, and simulated use and functional testing. The key studies summarized below demonstrate that the device is as safe, as effective, and performs as well or better than the legally marketed predicate device.

In addition, predicate device characterization testing was also performed.

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with ISO 10993. Testing included cytotoxicity, sensitization, irritation, oral toxicity, and genotoxicity. Other endpoints evaluated in the Biological Evaluation Report included subacute/subchronic toxicity and implantation.

Key Bench Testing

Dentinal Occlusion Testing: Dentinal occlusion testing was conducted to compare the subject and predicate devices with respect to their ability to occlude human dentine tubules. A scanning electron microscope (SEM) was used to capture images of the dentine samples and trained assessors graded the occlusion achieved by the test varnishes on a 5-point occlusion scale ranging from 1 (occluded) to 5 (unoccluded). SEM images of the dentine tubules of each sample were captured at 3000X magnification. One representative SEM image of the dentine tubules of each sample was additionally captured at 500X magnification. The study demonstrated that the subject device performed as well or better than the predicate device in occluding dentinal tubules.

Ion Release Testing: The subject and predicate devices were evaluated and compared with respect to the release of free fluoride and silver ions into deionized water solutions for 7 days. Both the subject and predicate devices were effective at releasing free fluoride ions and free silver ions once they were inserted into deionized water. Both devices had similar release profiles, with the majority of fluoride and silver ions released within the first 15 minutes. The percentages of silver released over 7 days was comparable between the subject and predicate devices.

Hydraulic Conductance Testing: The study used human dentine samples as the test substrate to evaluate the ability of a single application of four varnish treatments versus a negative control to occlude dentine tubules when assessed via hydraulic conductance. A worst-case formulation of the subject device with 2.72% sodium fluoride (vs. 3% in the final formulation) was compared against the predicate device (Elevate Advantage Arrest), Riva Star (K172047), Colgate PreviDent Varnish, and deionized water as a control. The mean percentage reduction in microfluidic flow was highest for Elevate Advantage Arrest, followed by Young formulation. The Young Varnish performed significantly better than the PreviDent Varnish and deionized water control. The Young Varnish also had a much larger reduction in flow than the Riva Star varnish, though the difference was not statistically significant.

Device Lifetime Testing: This study confirmed a variety of device attributes in a simulated device lifetime evaluation where the samples were subjected to approximately three times the exposure to air and sunlight as expected during normal use. The study demonstrated that the device and packaging configuration can withstand a typical device lifetime without experiencing any significant damage or product degradation.

Transportation Testing: Packaged product was exposed to hot, cold and ambient conditions and subjected to simulated shipping conditions according to ASTM D4169 Schedule 13 guidelines. Shipper boxes, unit boxes and product bottles were visually assessed for damage, legibility of labeling, evidence of leaking, and other attributes. All testing was successfully completed, demonstrating that the packaging configuration can withstand a distribution evaluation.

Shelf Life Testing

Accelerated and real-time stability studies of the subject device were conducted to support the proposed shelf life. The products were packaged in the intended packaging (including bottle with dispensing tip and cap) and subjected to accelerated conditions and evaluated at relevant time points. Product was evaluated for a range of functional and specification attributes after both accelerated and real-time conditions. All measures passed all tests for all test conditions to support the labeled shelf life.

Conclusions

The bench, biocompatibility and stability/shelf life studies demonstrated the subject device is (1) biocompatible; (2) maintains device and package integrity over the labeled shelf and usage life; and (3) has substantially equivalent performance to the predicate device with respect to dentinal tubule occlusion and silver and fluoride ion release. These results demonstrate that Young Silver

Fluoride Hypersensitivity Varnish is as safe, as effective, and performs as well or better than the legally marketed predicate device.

Summary

In summary, Young Silver Fluoride Hypersensitivity Varnish is substantially equivalent to the predicate Elevate Advantage Arrest varnish with respect to intended use, technological characteristics and performance. The biocompatibility and bench studies concluded that the device is as safe, as effective, and performs as well or better than the legally marketed predicate device.