November 21, 2025

Centrix, Inc.
% Joseph Azary
Regulatory Consultant
Aztech Regulatory & Quality LLC
543 Long Hill Avenue
Shelton, Connecticut 06484

Re: K250714
Trade/Device Name: FluoroDose Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH
Dated: October 23, 2025
Received: October 23, 2025

Dear Joseph Azary:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250714

Please provide the device trade name(s).

FluoroDose Varnish

Please provide your Indications for Use below.

Treatment of dental hypersensitivity and reduction of post-operative sensitivity.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
CENTRIX

K250714

FLUORODOSE VARNISH

1. SUBMITTER/510(K) HOLDER

Centrix Inc
770 River Road
Shelton, CT 06484

FDA Registration# 1281412

Contact Name: Joseph Azary (Aztech Regulatory & Quality LLC)
Email: jazary@erols.com
Telephone: (203) 242-6670

Date Revised: November 21, 2025

2. DEVICE NAME

Proprietary Name:	Centrix FluoroDose Varnish
Common/Usual Name:	Cavity Varnish
Classification Name:	Cavity Varnish
Classification Regulation:	21 CFR 872.3260
Product code:	LBH
Classification:	Class 2
Medical Specialty (Panel):	Dental

3. PREDICATE DEVICES

- Primary Predicate: Varnish America (Young Dental / MPL) K040098
- Secondary Predicate: Elevate SmartCoat 2.5% (FluoriMax) K131376
- Reference Predicate: 3M Clinpro 2.1% K231338

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4. DEVICE DESCRIPTION

The FluoroDose Varnish is a fluoride varnish available in mint flavor. FluoroDose varnish is sold in single-use Lollitrays, containing a 0.3ml dose and a Benda Brush applicator brush. The device is not sold as sterile and does not require sterilization prior to use. The product is offered in a 2.1% sodium fluoride variation and a 5% sodium fluoride variation. The device is used as a dentin desensitizer to be used by healthcare professionals including dentists and dental hygienists.

5. INDICATIONS FOR USE

Treatment of dental hypersensitivity and reduction of post-operative sensitivity.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Modifying the dentin surface to occlude the tubules is accepted as a useful approach to preventing dentin hypersensitivity. FluoroDose varnish contains suspensions of sodium fluoride in a rosin base.

The varnishes have identical regulatory classification, product codes, contraindications, mode of action, dispensing method, use of applicators, flavoring, shelf life, and being sold non-sterile.

While there may be some minor variations in wording the indications for use are equivalent in that all of the varnishes are for the treatment of hypersensitive teeth.

The fluoride amount and fluoride ions are equivalent between the 5% varnishes and the 2.1% varnishes.

The materials are equivalent in that all of the varnishes are based on the usage of rosin, sodium fluoride, beeswax, xylitol and flavor. There are some minor differences in the material formulations but are not considered significant concerns of safety or effectiveness.
The testing specifically included comparison to a predicate device to compare to a lower dose varnish and found that test results were equivalent.

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Device	Centrix Fluorodose Subject Device K250714	K040098 MPL VarnishAmerica 5% Primary Predicate	SmartCoat 2.5% NaF Varnish (K131376) Reference Device	3M Clinpro 2.1% (Reference, K231338) Reference Device	Comparison
Product Code	LBH	LBH	LBH	LBH	IDENTICAL
Regulation	21 CFR.872.3260 Cavity varnish	21 CFR.872.3260 Cavity varnish	21 CFR.872.3260 Cavity varnish	21 CFR.872.3260 Cavity varnish	IDENTICAL
Indications For Use – 510(k)	Treatment of dental hypersensitivity and Reduction of Post-Operative Sensitivity.	Treatment of dental hypersensitivity and Reduction of Post-Operative Sensitivity.	Intended for use on sensitive teeth, over-exposed dentin and root sensitivity and under temporary restorations or cements where post-operative sensitivity is of concern.	Treatment of hypersensitive teeth	All three devices are indicated for use in the treatment of hypersensitive teeth.
Contraindication	Ulcerative gingivitis and stomatitis Known allergic reactions to fluoride Avoid ingestion during	Ulcerative gingivitis and stomatitis Known allergic reactions to fluoride Avoid ingestion during application	None known per 510(k) Summary IFU includes ulcerative gingivitis and stomatitis.	None known per 510(k) Summary IFU includes ulcerative gingivitis and stomatitis.	IDENTICAL between subject device and primary predicate. SIMILAR between subject device and reference predicate

	application				
Intended User	Dental professional	Dental professional	Dental professional	Dental professional	IDENTICAL

Substantial Equivalency – Technological Characteristics					
Device	**Centrix Fluorodose**	**K040098 VarnishAmerica Primary Predicate**	**3M Clinpro 2.1% (K231338) Reference Predicate**	**SmartCoat 2.5% NaF Varnish (K131376) Secondary Predicate**	**Comparison**
Mode of Action	Dentin Tubule Occlusion	Dentin Tubule Occlusion	Dentin Tubule Occlusion	Dentin Tubule Occlusion	IDENTICAL
Dispensing Form	Single use of 0.3ml dose using supplied applicator brush	Single use of 0.4ml dose using supplied applicator brush	Single-use, unit-amount in LPop	Single Use Ampules of 1ml using supplied applicator Also available in Multi-use, multi-unit bottle 8ml or 12ml based on information available on company website	Subject device identical to primary predicate and 3M reference. The SmartCoat / FluoriMax is available for multiple use
Applicator	Disposable brush applicator	Disposable brush applicator	Disposable brush applicator	Disposable brush applicator	IDENTICAL
Fluoride Compound, Amount	Sodium fluoride (NaF), 2.1% and 5.0%	Sodium fluoride (NaF), 5%	Sodium fluoride (NaF), 2.1% (wt/wt)	Sodium fluoride (NaF), 2.5% (wt/wt)	IDENTICAL Subject device and Varnish America are both offered in 5% versions. SIMILAR Subject device and ClinPro and SmartCoat / FluoriMax have are range between 2.1% and 2.5%.
Flavoring	Available in Mint	Available in Mint	Available in Mint	Available in Mint	IDENTICAL
Amount of fluoride Ion	22,600 ppm for 5% version	22,600 ppm for 5% version	9,500 ppm for 2.1% version	11,300 ppm for 2.5% version	The fluoride ions are identical

	9500 ppm for 2.1% version				between 5% versions and 2.1% versions.
Releases Fluoride	Yes	Yes	Yes	Yes	IDENTICAL
Sterility	Non-sterile	Non-Sterile	Non-sterile	Non-sterile	IDENTICAL
Shelf Life	24 months	24 months	24 months	24 months	IDENTICAL
Materials	Sodium Fluoride Xylitol Rosin, Denatured Alcohol, Sodium Hydroxide, Beeswax, Sucralose, Flavor, Coloring	Sodium Fluoride Xylitol Rosin, Denatured Alcohol, Beeswax, Sucralose, Flavor	Sodium Fluoride Xylitol Polyacrylic acid, hydroxyethyl cellulose, calcium salt, phosphate salt, pH buffer, flavor, water, potassium sorbate	Sodium Fluoride Xylitol Shellac, propylene glycol, ethyl alcohol, dibasic sodium phosphate, ammonium phosphate, sucralose, calcium hydroxyapatite, flavor	IDENTICAL All of the products contain Sodium Fluoride, Xylitol and Flavoring. The subject device and Varnish America device have almost identical ingredients. DIFFERENCE The reference predicates have some different ingredients. The essential design of these products are the same as they are formulated with sodium fluoride with some different additives.

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Substantial Equivalency – Performance Bench Studies						
Physical Properties	**Test Method**	**Specification**	**Centrix Fluorodose**	**K040098 VarnishAmerica Primary Predicate**	**3M Clinpro 2.1% (K231338) Reference predicate**	**SmartCoat 2.5% NaF Varnish (K131376) Secondary Predicate**
Dentin tubule occlusion (In-vitro)	SEM	Comparison	Pass	Pass	Pass	Pass
Dentin Permeability	Internal Test	Comparison No statistically significant differences between the varnishes tested	2.1% = Average 99.19% 5% = Average 99.99%	N/A	N/A	2.5% = Average 99.89%
3 Day Fluoride Release	Centrix Internal Test Method	Comparison for release of fluoride during first 2 hours	2.1% and 5% Release burst of fluoride in first 2 hours	Not tested Data not known	Not tested Data not known	Release burst of fluoride in first 2 hours.
Fluoride Release	ISO 17730-2020	Pass/Fail: Fluoride release per ISO 17330 *Confirmed through internal testing ++Confirmed through 510(k) Summary / Available Information	Pass*	Pass++	Pass++	Pass*

7. PERFORMANCE TESTING

The following testing was performed and where applicable consensus standards were utilized.

Summary of Testing

Standard	Description of Test	Results
ISO 10993-5 (2009) Cytotoxicity	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity	The testing found the subject device was classified as cytotoxic but performed similarly to the predicate devices. The Biological Evaluation Report examined biocompatibility in its entirety and concluded that the materials did not exhibit concerns.
ISO 10993-10 (2021)	Biological Evaluation of Medical Devices – Part 10: Tests for Skin Sensitization	The testing concluded that the subject device is NOT considered to be a sensitizer.
ISO 10993-23 (2021)	Biological Evaluation of Medical Devices – Part 23: Tests for Irritation	The testing concluded that the subject device is considered to be a Non-Irritant to oral mucosa.
ISO 10993-11 (2017)	Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity	Systemic Injection testing concluded that the device did not induce significantly greater biological reaction than the control extracts following a single dose to albino Swiss mice. The testing met requirements of ISO 10993-11.
N/A	SEM Analysis of Subject Device (both 2.1% and 5%) and Predicate Device	The SEM report summarizes comparison between subject device and predicate device on human tooth samples. The testing concluded that all of the varnishes tested provided occlusion of open tubules. The Centrix product deposited observable varnish within tubules.
ISO 17730	Fluoride Release Testing. Evaluation of fluoride release including the subject device (2.1% and 5%) and predicate device.	The study concluded that all varnishes tested passed requirements of ISO 17730 for fluoride release.
ISO 17730	Total Fluoride Content testing of subject device (2.1% and 5%)	The study concluded that the fluoride content matched the labeled amount (for 2.1% and 5%) as required by ISO 17730.
N/A	Dentin Permeability. Human molar teeth samples were evaluated to calculate the % reduction of dentin permeability. The testing included the subject device (2.1% and 5%) and predicate device.	The results found that there was no statistically significant difference for reduction of dentin permeability between subject device (2.1% and 5%) and subject device.
N/A	3 Day Fluoride Release test for subject device (2.1% and 5%) and predicate device.	The testing concluded that all varnishes tested released burst of fluoride within the first 2 hours.

8. SAFETY AND EFFICACY

The subject device is found to be equivalent to the primary predicate device, secondary predicate and reference predicate based on comparative evaluation and testing. The overall safety and efficacy of the subject device has been demonstrated through testing conducted on the subject device as well as comparative testing between subject and predicate device.

9. CONCLUSION

Information presented supports substantial equivalence of the subject device to the predicate devices based on similarities in intended use, design, principles of operation, performance specifications, and testing.

Centrix Inc believes that based on the indications for use, technological characteristics, and comparison to predicate devices the subject device has been shown to be substantially equivalent to the predicate and the minor differences do not impact safety and effectiveness.