October 27, 2023

Centrix Inc
℅ Joseph Azary
Chief Advisor & Compliance Officer
Aztech Regulatory & Quality LLC
543 Long Hill Avenue
Shelton, Connecticut 06484

Re: K222459
Trade/Device Name: Centrix FluoroSilver Silver Diamine Fluoride 38%
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity varnish
Regulatory Class: Class II
Product Code: PHR
Dated: August 12, 2022
Received: August 15, 2022

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.

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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222459

Device Name
Centrix FluoroSilver Silver Diamine Fluoride 38%

Indications for Use *(Describe)*
Treatment of Dental Hypersensitivity for use in adults over the age of 21.

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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K222459

510(k) Summary

CENTRIX FLUOROSILVER SILVER DIAMINE FLUORIDE 38%

1. SUBMITTER/510(K) HOLDER

Centrix Inc
770 River Road
Shelton, CT 06484

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

Date Prepared: October 26, 2023

2. DEVICE NAME

Proprietary Name:	Centrix FluoroSilver Silver Diamine Fluoride 38%
Common/Usual Name:	Tooth Desensitizer
Classification Name:	Tooth Desensitizer
Classification Regulation:	21 CFR 872.3260
Product code:	PHR
Classification:	Class 2
Medical Specialty (Panel):	Division of Dental and ENT devices

3. PREDICATE DEVICES

- ***Advantage Arrest*** (Elevate Oral Care aka ADP Silver Dental Arrest) K102973

4. DEVICE DESCRIPTION

The Centrix FluoroSilver is a professional tooth desensitizer that is composed of Aqueous Silver Diamine Fluoride, 38.3% to 43.2% w/v. The solution is composed of water, ammonia, fluoride, silver and a colorant.

The device is provided in a single 5 ml squeezable dropper bottle or a multi-pack which includes three 5 ml squeezable dropper bottles. Each variation is packaged in a preformed tray and includes applicators (more information provided below) and the Instructions for Use (IFU).

The primary mode of action is to reduce dentinal hypersensitivity by occluding open dentin tubules by the formation of a precipitate.

The dentist must clean and dry the affected tooth surface and then dispense 1-2 drops of solution into a disposable dappen dish. The material is applied directly to the tooth surface using Centrix supplied applicators (Centrix Benda Micro Fine Brushes). The tooth must be allowed to air dry and then if needed one or two reapplications can be administered at intervals of one week.

The packaging will labeled with lot number, expiration date and UDI barcode. The shelf life of the device is 24 months.

The device is packaged with applicators (Centrix Benda Micro Fine Brushes) that are classified as class I 510(k) exempt medical devices under regulation 21 CFR 872.3140, Product Code KXR. A quantity of applicators will be provided in a zip lock bag.

The primary mode of action is to reduce dentinal hypersensitivity by occluding open dentin tubules by the formation of a precipitate.

Specifications

Parameter	**Specification**
Silver Diamine Fluoride (SDF)	360 – 400 g/L
Fluoride	50 – 60 g/L
pH	8.5 – 9.5
Density	1.265 – 1.276 g/L

5. INDICATIONS FOR USE

Treatment of Dental Hypersensitivity for use in adults over the age of 21.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The solution is applied to the tooth enamel to block dentinal tubules for the purpose of reducing tooth sensitivity. The solution precipitates upon application resulting in a physical blockage of dentinal tubules.

The subject device has equivalent indications for use, technical characteristics, mode of action, material composition (confirmed through chemical identity testing), SDF % and cytotoxicity results (comparative cytotoxicity testing) when compared to the selected predicate device.

Additionally, the subject device has a different colorant, uses different size bottles, and some minor differences in wording in labeling. These differences are minor and the overall similarities support the equivalence between the subject and predicate device.

Comparison Table

	Centrix FluoroSilver Silver Diamine Fluoride 38%	**Advantage Arrest**	**Discussion**
510(k) Number	K222459	K102973	
Company	Centrix Inc	Elevate Oral Care (named as ADP Silver Dental Arrest LLC in 510k)	
Classification Name	Cavity Varnish	Cavity Varnish	IDENTICAL
Common Name	Tooth Desensitizer	Tooth Desensitizer	IDENTICAL
Regulation Number	872.3260	872.3260	IDENTICAL
Product Code	PHR	PHR	IDENTICAL
Indications for Use	Treatment of Dental Hypersensitivity for use in adults over the age of 21.	Treatment of dentinal hypersensitivity. For use in adult over the age of 21.	IDENTICAL
Technical Method / Characteristics	Silver diamine fluoride forms precipitates with calcium or phosphate in the dentinal tubules to block open dentinal tubules.	Silver diamine fluoride forms precipitates with calcium or phosphate in the dentinal tubules to block open dentinal tubules.	IDENTICAL
Mode of Action	Tubule occlusion	Tubule occlusion	IDENTICAL
Material Composition	Silver diamine fluoride Purified Water	Silver diamine fluoride Purified Water	IDENTICAL

	Fast Green FCF Dye	FD&C Blue 1	
Chemical Composition Profile	HPLC – Mass Spec	HPLC Mass Spec	Nearly Identical – Compositional Equivalency
Color	Green	Blue / Violet	IDENTICAL
% SDF	38%	38%	IDENTICAL
Application	Liquid	Liquid	IDENTICAL
Rx / OTC	Rx	Rx	IDENTICAL
Packaging	Squeezable Dropper Bottle 5 ml bottle Three 5ml bottle kit Applicator(s)	Squeezable Dropper Bottle 8ml bottle Three 3ml bottle kit	IDENTICAL Packaging type Different Size bottles
Cytotoxicity	Yielded positive cytotoxicity when tested to ISO 10993-5	Yielded positive cytotoxicity when tested to ISO 10993-5	IDENTICAL
Fluoride Release	0.023 +/- 0.003 ppmF/mm^2	0.024 +/- 0.006 ppmF/mm^2	IDENTICAL No statistical difference between devices.
SEM Analysis	Silver deposition on dentin and in tubules between Centrix SDF and Elevate SDF showed no discernable difference based on SEM analyses.		IDENTICAL No discernable difference between devices.
Dentin Permeability	Dentin Permeability. Human molar teeth samples were evaluated to calculate the % reduction of dentin permeability using the ratio of average treated volume of water passing through the dentin divided by the average baseline rate of flow. The results found that tooth samples treated with the subject and predicate device reduced the dentin permeability by an average 97.5%. Dentin permeability is thought to be related to dentin sensitivity. Treatments that reduce dentin permeability have been found to stop pain due to dentin sensitivity. Centrix % Reduction in Dentin Permeability 97.5% +/- 4.3% Elevate % Reduction in Dentin Permeability 97.5% +/- 2.5%		IDENTICAL

7. PERFORMANCE TESTING

The following standards were either used as a reference and/or for testing of the subject device:

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	Cytotoxicity testing was conducted on both the subject (Centrix) and predicate (Elevate) devices. The testing found both the subject device and predicate device samples were "unsuitable for analysis" due to the high level of precipitate generated when the test articles were combined with culture media. The subject device performed identically to the predicate device.
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 contact skin 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	Acute Systemic Toxicity testing was conducted on both the subject device (Centrix) and Predicate Device (Elevate). The testing concluded that there were no signs of gross toxicity, adverse clinical effects, or abnormal behavior. No gross abnormalities were noted after a 3 day observation and necropsy. Both the subject and predicate devices met the requirements of the tests and performed identically.
ISO 10993-1 (2018)	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process	The remaining biological endpoints of Acute, Subacute / Subchronic, Chronic Systemic Toxicity, Genotoxicity and Carcinogenicity were evaluated and documented in a Toxicological Risk Assessment report. The evaluation concluded that information gathered in published literature on the chemical ingredients, intended use, predicate device information that the risk of adverse effects are low with respect to biological endpoints of Acute, Subacute / Subchronic, Chronic Systemic Toxicity, Genotoxicity and Carcinogenicity.
N/A	SEM Analysis of Subject and Predicate Devices	The SEM report summarizes comparison between subject device (Centrix SDF) and predicate device (Elevate SDF) on human tooth samples. Both the subject and predicate devices treated teeth samples have significant deposits of silver on the cut

		surface of the tooth and within the dentinal tubules. There is no discernable difference in the silver deposited on the tooth surface and within the dentinal tubules as a result of exposure to subject and predicate devices.
N/A	Fluoride Release Testing. Evaluation of fluoride release in SDF treated tooth cross sections comparing Centrix FluoroSilver Silver Diamine Fluoride 38% and Predicate Device (Elevate Advantage Arrest SDF)	The study confirmed the release of fluoride at the same rate with no statistical difference between the groups. The maximum fluoride concentrations were equivalent. Subject 0.023 +/- 0.003 ppmF/mm^2 Predicate 0.024 +/- 0.006 ppmF/mm^2
N/A	Dentin Permeability. Human molar teeth samples were evaluated to calculate the % reduction of dentin permeability using the ratio of average treated volume of water passing through the dentin divided by the average baseline rate of flow.	The results found that tooth samples treated with SDF reduced the dentin permeability by 97.5%. Dentin permeability is thought to be related to dentin sensitivity. Treatments that reduce dentin permeability have been found to stop pain due to dentin sensitivity
N/A	Chemical Identity Testing: Mass Spectrometry (MS) performed on subject and predicate device solutions	MS analysis found a strong match for chemical composition between the subject and predicate device to demonstrate compositional equivalency.

8. SAFETY AND EFFICACY

The subject device is found to be equivalent to the predicate device based on comparative evaluation and testing. The overall safety and efficacy of FluoroSilver Silver Diamine Fluoride 38% usage for treating dentinal sensitivity has been demonstrated through testing conducted on the subject device, comparative testing between subject and predicate device and published literature.

9. CONCLUSION

Information presented supports substantial equivalence of the Centrix FluoroSilver Silver Diamine Fluoride 38% the predicate device 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 Centrix FluoroSilver Silver Diamine Fluoride 38% has been shown to be substantially equivalent to the predicate and have demonstrated that the device is as safe and as effective as the predicate.