May 10, 2023

3M ESPE Dental Products
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K231338
Trade/Device Name: 3M™ Clinpro™ Clear 2.1% Sodium Fluoride Treatment
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity varnish
Regulatory Class: Class II
Product Code: LBH
Dated: May 8, 2023
Received: May 8, 2023

Dear Prithul Bom:

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 -S

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)*
K231338

Device Name
3M™ Clinpro™ Clear 2.1% Sodium Fluoride Treatment

Indications for Use *(Describe)*
3M™ Clinpro™ Clear 2.1% Sodium Fluoride Treatment is indicated for the treatment of hypersensitive teeth.

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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3M™ Clinpro™ Clear
2.1% Sodium Fluoride Treatment – 510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 CFR §807.92

Submitter Information

510(k) Submitter…… 3M ESPE Dental Products
2510 Conway Avenue
St. Paul, MN 55144, USA
Establishment Registration No.: 3005174370

Primary Contact…… Chandrapaul Parsram, M.S.
Regulatory Affairs Associate
Phone: (651) 467 3014
cparsram@mmm.com

Submission Date……April 28th, 2023

Subject Device Information

Proprietary Trade Name……. 3M™ Clinpro™

Device Name……..…2.1% Sodium Fluoride Treatment

Common Name……. Cavity varnish

Classification Name……..… Cavity varnish

Regulation Number……. 21 CFR § 872.3260

Product Code…….....……. LBH

Classification Panel……..…. Dental Products

Classification…….....….Medical Device, Class II

Predicate and Reference Devices:

Product Name	**3M Vanish Varnish (Primary Predicate)**	**Fluor Protector S (Reference)**
Manufacturer	3M ESPE Dental Products 2510 Conway Avenue Saint Paul, MN, 55144	IVOCLAR VIVADENT AG 175 PINEVIEW DR. AMHERST, NY 14228
510(k) Number	K092141	K131487
Device Class	2 – LBH (Cavity varnish)	2 – LBH (Cavity varnish)

Description of Device

3M™ Clinpro™ Clear 2.1% Sodium Fluoride Treatment is an aqueous fluoride coating that is applied topically to the tooth surfaces for the treatment of hypersensitive teeth. The product is sweetened with xylitol and sucralose. Clinpro 2.1% Sodium Fluoride Treatment contains 9,500 ppm fluoride and added calcium and phosphate. 3M Clinpro Clear 2.1% Sodium Fluoride Treatment uses the L-Pop™ unit dose dispensing system designed by 3M. Each L-Pop contains 0.5 ml (0.5 grams) of the coating and is offered in mint and melon flavors and a flavorless version.

Indications for Use

3M Clinpro Clear 2.1% Sodium Fluoride Treatment is indicated for the treatment of hypersensitive teeth.

Substantial Equivalence

Substantial equivalency of 3M Clinpro Clear 2.1% Sodium Fluoride Treatment (subject device) to 3M™ Vanish™ Varnish (primary predicate) and Fluor Protector S (reference) is made on the basis of intended/indicated use, technological characteristics, and performance testing according to the Agency's *Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* dated July 28, 2014.

Substantial Equivalence - Intended/Indicated Use				
Device	**3M Clinpro Clear 2.1% Sodium Fluoride Treatment (Subject Device)**	**3M Vanish Varnish (Primary Predicate, K092141)**	**Fluor Protector S (Reference, K131487)**	**Comparison**
Product Code	LBH	LBH	LBH	Identical
Regulation	21 CFR.872.3260 Cavity varnish	21 CFR.872.3260 Cavity varnish	21 CFR.872.3260 Cavity varnish	Identical
Intended Use per Regulation	Fluoridated tooth coating.	Fluoridated tooth coating.	Fluoridated tooth coating.	Identical
Indications for Use – 510(k)	Clinpro Clear 2.1% Sodium Fluoride Treatment is indicated for the treatment of hypersensitive teeth.	•Treatment of hypersensitive teeth • Use on exposed dentin and root sensitivity • Under temporary restoratives and cements where post-operative sensitivity is of concern	•Treatment of dentinal hypersensitivity •Treatment of exposed cervical •Treatment of sensitivity after tooth whitening	All three devices are indicated for use in the treatment of hypersensitive teeth. Both the subject device and primary predicate device are indicated for use in the treatment of hypersensitive teeth. Fluor Protector S also has the same indication, expressed as dentinal hypersensitivity.
Contraindication	None known.	Ulcerative gingivitis and stomatitis	If patients are known to be allergic to any of the ingredients of Fluor Protector S, the material should not be used.	Different – Subject device is not contraindicated for use in patients with ulcerative gingivitis and stomatitis because it is not formulated with a colophony polymer. The subject device does not have any known contraindications.
Intended User	Dental professional	Dental professional	Dental professional	Identical

Substantial Equivalency – Technological Characteristics				
Device	**3M Clinpro Clear 2.1% Sodium Fluoride Treatment (Subject Device)**	**3M Vanish Varnish (Primary Predicate, K092141)**	**Fluor Protector S (Reference, K131487)**	**Comparison – Are the technological characteristics different?**
Mode of Action	Dentin Tubule Occlusion	Dentin Tubule Occlusion	Dentin Tubule Occlusion	Same
Dispensing Form	Single-use, unit-amount in L-Pop	Single-use, unit-amount in Sachet	Single-use, unit-amount ampoule Multi-use, multi-unit tube	Same
Applicator	Disposable brush applicator	Disposable brush applicator	Disposable brush applicator	Same
Fluoride Compound, Amount	Sodium fluoride (NaF), 2.1% (wt/wt)	Sodium fluoride (NaF), 5% (wt/wt)	Ammonium fluoride (NH_4F), 1.5% (wt/wt)	Different; however, 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	9,500 ppm	22,500 ppm	7,700 ppm	
Releases Fluoride	Yes	Yes	Yes	Same
Releases Phosphate	Yes	Yes	Not designed to release phosphate	Same
Releases Calcium	Yes	Yes	Not designed to release calcium	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
Shelf Life	24 months	24 months	Unknown	Same
Materials	Polyacrylic acid, hydroxyethyl cellulose, calcium salt, phosphate salt, pH buffer, flavor, sodium fluoride, water, xylitol, potassium sorbate	colophony resin, n-hexane, ethyl, alcohol, sodium fluoride, food grade flavor, flavor enhancer, thickener, modified tricalcium phosphate	Ethanol/water, polymer, additive, ammonium fluoride, saccharin, mint aroma	Different; however, different questions of safety or effectiveness are not raised because significant concerns are not raised. 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.

Substantial Equivalency – Performance Bench Studies					
Physical Properties	**Test Method**	**Specification**	**3M Clinpro Clear 2.1% Sodium Fluoride Treatment (Subject Device)**	**3M Vanish Varnish (Primary Predicate, K092141)**	**Fluor Protector S (Reference, K131487)**
Dentin tubule occlusion (In-vitro)	SEM	Pass/Fail: Must visually occlude (cover) exposed dentin tubules	**Pass**	**Pass**	**Pass**
Dentin fluid flow reduction (In-vitro)	Modified Pashley Test	Pass/Fail: Must demonstrate visual reduction in fluid flow when treated compared to when they were untreated	**Pass**	**Pass**	**Pass**
Fluoride Release	ISO 17730-2020	Pass/Fail: Fluoride release potential is ≥ 14 µg F/mm^2 after 60 minutes	**Pass**	**Pass**	**Pass**
	Internal 3M Test Method	Pass/Fail: Cumulative fluoride release potential at 1 hour is >0 µg/cm^2/g	**Pass**	**Pass**	**Pass**
		Pass/Fail: Cumulative fluoride release potential at 24 hours is >0 µg/cm^2/g	**Pass**	**Pass**	**Pass**
Calcium Release	ICP-AES	Pass/Fail: Cumulative calcium release potential at 1 hour is >0 µg/cm^2/g	**Pass**	**Pass**	Not tested – not claimed by the manufacturer.
		Pass/Fail: Cumulative fluoride release potential at 24 hours is >0 µg/cm^2/g	**Pass**	**Pass**	
Phosphorus (Phosphate) Release	ICP-AES	Pass/Fail: Cumulative phosphorus (phosphate) release potential at 1 hour is >0 µg/cm^2/g	**Pass**	**Pass**	
		Pass/Fail: Cumulative phosphorus (phosphate) release potential at 24 hours is >0 µg/cm^2/g	**Pass**	**Pass**	
Consistency	Internal 3M Test Method	Pass/Fail: The reading number of 1/32th inch is 32-52.	**Pass**	**Pass**	Not applicable. 3M requirement.
pH	Internal 3M Test Method	Pass/Fail: 6.0-8.0	**Pass**	**Not applicable.**	**Pass**

Biocompatibility Assessment

A Diplomate of the American Board of Toxicology has assessed this product's safety and determined that it is safe for its intended use. 3M Clinpro Clear 2.1% Sodium Fluoride Treatment was assessed as a surface medical device in contact with mucosal membrane for less than or equal to 24 hours (ISO 10993, ISO 7405, FDA-2013-D-0350, and PFSB). In accordance with the combined guidance found in ISO 10993, ISO 7405, Testing guidelines outlined in the US FDA Docket Number FDA-2013-D-0350, and Japan: PSEHB/MDED No. 0106-1 and 0612-4, the following endpoints must be considered in the biocompatibility evaluation of this product: Physical and/or Chemical Information, Cytotoxicity, Sensitization, and Irritation/Intracutaneous Reactivity. In addition, Acute Systemic Toxicity and Pulp/Dentin effects were assessed.

Conclusion

3M Clinpro Clear 2.1% Sodium Fluoride Treatment has the same intended use as 3M Vanish Varnish and Fluor Protector S. In addition, all three devices are indicated for use in the treatment of hypersensitive teeth. 3M Clinpro Clear 2.1% Sodium Fluoride Treatment has similar but not identical technological characteristics to the predicate device. Minor differences in the technological characteristics include a difference in the amount of fluoride and material formulations. These differences do not raise different questions of safety or effectiveness because significant concerns about safety or effectiveness are not raised for the subject device. Bench testing was conducted to compare the performance of 3M Clinpro Clear 2.1% Sodium Fluoride Treatment to 3M Vanish Varnish and Fluor Protector S. In addition, biocompatibility studies were completed. All testing demonstrates the safety and performance of 3M Clinpro Clear 2.1% Sodium Fluoride Treatment are substantially equivalent to the predicate device.