July 24, 2023

Kettenbach GmbH & Co. KG
Katja Simon
Regulatory Affairs Manager
Im Heerfeld 7
Eschenburg, Hessen 35713
GERMANY

Re: K230333
Trade/Device Name: Profisil Fluoride Varnish Combi pack (14801), Profisil Fluoride Varnish Normal pack mint (14802), Profisil Fluoride Varnish Normal pack berry (14804), Profisil Fluoride Varnish Normal pack unflavored (14806), Profisil Fluoride Varnish Sample pack (14800)
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH
Dated: June 22, 2023
Received: June 22, 2023

Dear Katja Simon:

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.

Submission Number *(if known)*

K230333

Device Name

Profisil Fluoride Varnish Combi pack (14801);
Profisil Fluoride Varnish Normal pack mint (14802);
Profisil Fluoride Varnish Normal pack berry (14804);
Profisil Fluoride Varnish Normal pack unflavored (14806);
Profisil Fluoride Varnish Sample pack (14800)

Indications for Use *(Describe)*

Profisil® Fluoride Varnish is a 5 % sodium fluoride varnish which produces mechanical occlusion of the dentinal tubules in the treatment of tooth 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.

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510(k) Summary - K230333

I. Submitter:

Kettenbach GmbH & Co KG
Im Heerfeld 7
35713 Eschenburg
Germany

Phone: +49 2774 705 0
Fax: +49 2774 705 66

Contact person:
Simon, Katja
Regulatory Affairs Manager
Im Heerfeld 7
35713 Eschenburg
Germany
Phone: + 49 277 4705 0
E-mail: katja.simon@kettenbach.com

Date of preparation: July 24th, 2023

II. Device

Name of Device:	Profisil® Fluoride Varnish
Common or Usual Name:	Profisil® Fluoride Varnish
Classification Name:	Dental, Varnish, Cavity (21 CFR 872.3260)
Regulatory Class:	II
Product Code:	LBH

III. Predicate devices:

Vanish™ Varnish (3M Espe), K092141
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. Device Description:

Profisil® Fluoride Varnish is designed to securely adhere to the tooth surface for several hours while releasing fluoride ions. The varnish contains 5 % sodium fluoride suspended in a mucosa-friendly, pleasantly flavored dimethicone gel. The varnish is available in following versions: mint, berry and unflavored.

V. Indications for Use:

Profisil® Fluoride Varnish is a 5 % sodium fluoride varnish which produces mechanical occlusion of the dentinal tubules in the treatment of tooth hypersensitivity.

VI. Table 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Predicate Devices	Substantial Equivalent Device	Conclusion
Product	Vanish Varnish	Profisil®	
Manufacturer	3M Espe	Kettenbach GmbH & Co. KG	
Product Description	3M™ ESPE™ Vanish™ Varnish 5% Sodium Fluoride White Varnish is a 22.600 ppm fluoride-containing varnish for application to enamel and dentin for the treatment of hypersensitivity teeth. It will spread on and adhere to moist teeth. Vanish varnish is an alcohol-based solution of modified rosin. The product is sweetened with xylitol. Vanish varnish contains an innovative tri-calcium phosphate (TCP) ingredient exclusively from 3M. The ingredient TCP serves as a source of bioavailable calcium and phosphate ions when the varnish is applied to the teeth. Calcium and phosphate ions are naturally occurring components of saliva long associated with maintaining healthy teeth.	Profisil® Fluoride Varnish is designed to securely adhere to the tooth surface for several hours while releasing fluoride ions. The varnish contains 5 % sodium fluoride suspended in a mucosa-friendly, pleasantly flavored dimethicone gel. The varnish is available in following versions: mint, berry and unflavored.	Treatment of hypersensitivity teeth is the technological principle for both the subject and predicate devices. The content of sodium fluoride is identical. The following differences exist between the subject and the predicate device: Profisil ® does not contain TCP
Intended purpose	5% Sodium Fluoride Varnish for the treatment of dentinal hypersensitivity	5% Sodium Fluoride Varnish indicated for the treatment of dentinal hypersensitivity.	The intended purpose is identical
Indication	• Treatment of hypersensitive teeth • Use on exposed dentin and root sensitivity • Under temporary restoratives and cements where post-operative sensitivity is of concern	Profisil® Fluoride Varnish is a 5 % sodium fluoride varnish which produces mechanical occlusion of the dentinal tubules in the treatment of tooth hypersensitivity.	The indication is the same and are intended for the same general population of patients, experiencing dentinal hypersensitivity. Both devices produce an occlusion of the dentinal tubules in the treatment of tooth hypersensitivity.
Basic formulation	• Colophony / Polyamide resin • Ethyl alcohol • Flavor • 5% Sodium fluoride	• Silicone Encapsulant • Thickener/ Adhesive • Flavor / Sweetener • 5% Sodium fluoride	The percentage of sodium fluoride is identical. However, Profisil does not contain TCP

	Predicate Devices	Substantial Equivalent Device	Conclusion
Product	Vanish Varnish	Profisil®	
Manufacturer	3M Espe	Kettenbach GmbH & Co. KG	
Mode of action / technology	Dentin tubule occlusion The material acts to physically block or occlude patent/open dentin tubules on the dentition. Vanish Varnish has unit-dose packages delivering up to 0.25 mL to 0.4 mL of 5% sodium fluoride. However, this product contains substances that may cause an allergic reaction by skin contact in certain individuals.	Dentin tubule occlusion The material acts to physically block or occlude patent/open dentin tubules on the dentition.	Same mode of action.
Single use	Single use only	Single use only	Identical, both are single use devices
Method of application	Unit-dose packages delivering up to 0.25 ml or 0.4ml of 5% sodium fluoride varnish. Varnish and an applicator brush placed in a molded tray and closed with a seal	Unit-dose packages delivering in 0.5ml of 5% sodium fluoride varnish. Varnish and an applicator brush placed in a molded tray and closed with a seal	The delivery systems and the mode of application are similar.
Contraindications / Precautions	This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known colophony allergies. Discontinue patient's use of other prescriptive fluoride preparations for 24 hours following Vanish Varnish 5% sodium fluoride varnish application. Children taking fluoride supplements should discontinue for 1-3 days following treatment.	Do not use this product on any individual who has a known intolerance to fluoride. If any signs of inflammation or allergic reaction occur, discontinue use immediately and refrain from further use with this patient. Other prescription products containing fluoride should not be used within 24 hours of using the varnish. Patients using regular, systemic fluoridation should stop using these products for three days following use of this varnish	Discontinue patient's use of other prescriptive fluoride preparations for 24 hours / three days is similar
Shelf Life	24 months	24 months	The shelf life is identical
Performance testing	A comparison of the parameters in respect, pH value, dynamic viscosity, fluoride release and electron microscopy (SEM) studies were performed. The results demonstrated the substantial equivalence to the predicate device.		
Summary of Product Description,	The indication of the subject device is the same for the predicate device. Contraindications, application, and side effects for both products are basically the same – there is a slight difference in the wording.		

	Predicate Devices	Substantial Equivalent Device	Conclusion
Product	Vanish Varnish	Profisil®	
Manufacturer	3M Espe	Kettenbach GmbH & Co. KG	
Intended purpose Indications, Contraindications / Precautions			
Summary Chemical Composition	The Profisil® formulation has been thoroughly assessed for biocompatibility.		
Summary of Finished Device Specification	According to EN ISO 17730:2020 "Dentistry – fluoride varnishes" apart from the total fluoride, no other properties appear as being relevant for having the device functioning or performing as intended. Specific physical properties have been assessed and verified according to product standard EN ISO 17730:2020 – Dentistry- fluoride varnishes". The acceptance criteria of EN ISO 17730:2020 was fulfilled.		

VII. Performance Data:

Biocompatibility:
The following performance data were provided in support of the substantial equivalence determination. The biocompatibility evaluation for Profisil® Fluoride Varnish was conducted in accordance with ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.:

- Cytotoxicity ISO 10993-5
- Sensitization ISO 10993-10
- Irritation ISO 10993-23
- Pyrogenicity ISO 10993-11
- Systemic toxicity ISO 10993-11

To evaluate the biological safety of Kettenbach's Fluoride Varnish, consideration was given to the type of patient contact, the potential hazards associated with the chemicals used in the devices, and historical use of the materials used in the devices. Profisil® Fluoride Varnish is considered to have met the requirements of ISO 10993-1:2018, ISO 7405:2018, FDA's Use of International standard ISO 10993-1, and the European Union Medical Regulation (EU) 2017/745 is an externally communicating device with limited (<24 hours) contact with the patient's tissue/bone/dentin and can be considered safe for use.

Non-clinical performance:
According to EN ISO 17730:2020 "Dentistry – fluoride varnishes" apart from the total fluoride, no other properties appear as being relevant for having the device functioning or performing as intended.
Specific physical properties have been assessed and verified according to product standard EN ISO 17730:2020 – Dentistry- fluoride varnishes".
The acceptance criteria of EN ISO 17730:2020 was fulfilled.

- pH value
- Dynamic viscosity
- Fluoride release
- Electron microscopy (SEM) study

Summary:
Based on the performance data, Profisil® Fluoride Varnish was found to have a safety and effectiveness profile that is similar to the predicate device.

Clinical Performance Data:
Data from clinical studies was not provided.

VIII. Conclusion:

Kettenbach Profisil® Fluoride Varnish is comprised of a highly substantive and highly viscous dimethicone gel carrier containing a suspension of 5% sodium by weight sodium fluoride crystals.

The material acts to physically block or occlude patent/open dentin tubules on the dentition. This is achieved by applying the sodium fluoride dimethicone gel with an applicator brush to the affected dentition. The gel is allowed to penetrate the porosity of the tooth structure and block these open pores. The sodium fluoride reacts with calcium to form insoluble calcium fluoride to create a semi-permanent occluding material to alleviate the effect of dentinal hypersensitivity.

Profisil® Fluoride Varnish is substantially equivalent to the predicate device 3M Vanish Varnish in the indications for use and mechanism of action. Both products are intended for the reduction of dentinal hypersensitivity, and both produce this effect by the mechanical occlusion of the open dentinal tubules upon and within the dentition. Both Kettenbach Profisil® Fluoride Varnish and 3M Vanish Varnish are applied in an identical manner and are intended for the same general dental population.

Laboratory data demonstrate both products are equivalent in efficacy and release fluoride at an equivalent rate.