July 18, 2024

Elevate Oral Care
Steven Pardue
Managing Member
346 Pike Rd
Suite 5
West Palm Beach, Florida 33411

Re: K233768
Trade/Device Name: Papacarie Duo
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH, KLE
Dated: [NOTE: Use date of most recent supplement]
Received: June 18, 2024

Dear Steven Pardue:

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., 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)*

K233768

Device Name

Papacarie Duo

Indications for Use *(Describe)*

Papacarie Duo is a gel cleanser intended to clean the interior of a prepared cavity of a tooth prior to self-etch bonding procedures.

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: K233768

Submitter:

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Country:	USA
Correspondent:	Steve Pardue Managing Member
Phone:	877-866-9113
Fax:	561-244-1927
Email:	spardue@elevateoralcare.com
Date:	July 18 2024

Name of Device

Proprietary Name:	Papacarie™ Duo
Classification Name:	Varnish, Cavity 21 CFR 872.3260 as Class II device Product Code: LBH, KLE
Common Name:	Cavity Varnish

Predicate Devices

Predicate Device	510(k)	Product Code
FiteBac Cavity Cleanser	K190271	LBH
Clean and Boost Dentin & Enamel Cleanser	K120620	KLE

Description

Papacarie Duo is a light blue colored gel cleanser dispensed from a prefilled, multi-use syringe storage system to a mixing pad, then applied to the interior of a prepared tooth cavity by dental professionals using a flocked tip brush or micro brush (not included). The tooth cavity is rinsed with water 60 seconds after application and prior to application of self-etch bonding material. The formula has a light blue color for easier visualization when it is applied on tooth surfaces. For single application prior to self-etch bonding procedure.

Indications for Use

Papacarie Duo is a gel cleanser intended to clean the interior of a prepared cavity of a tooth prior to self-etch bonding procedures.

Comparison of the Indication for Use of Papacarie Duo to the Predicate Devices

Papacarie Duo Indication for Use	Clean & Boost Dentin & Enamel Cleanser, Indication for Use, K120620	FiteBac Cavity Cleanser
Papacarie Duo is a gel cleanser intended to clean the interior of a prepared cavity of a tooth prior to self-etch bonding procedures.	Clean and Boost is an acidic, aqueous cleanser that has been designed to help remove contaminants from the surface of a tooth prior to bonding. These contaminants can be hand piece oil, tooth debris, or imaging powder (used to create digital impressions for CAD/CAM restorations).	The FiteBac® Cavity Cleanser is a 2% K21 QAS aqueous ethanolic solution intended for cleansing and moistening/rewetting of cavity preparations.

Technological Characteristics

The chemical composition of Papacarie Duo, while different than the predicate devices has the same intended function as both predicate devices, to clean the prepared cavity in a tooth. The use for Papacarie Duo is highly similar to the predicates indications for use as both devices are used in a prepared cavity in a tooth prior to bonding as part of tooth restoration procedures and any differences do not raise concerns of safety or effectiveness.

The predicate device Clean and Boost uses strong acid to clean prepared cavities while the second predicate device uses ethanol and quaternary ammonium silane to clean surfaces. All products use different technological methods to clean prepared tooth surfaces. Papacarie Duo uses papain and propylene glycol as cleansers to clean these surfaces. These different technological characteristics do not present different questions of safety and effectiveness.

Papain has been used in food preparation and as ingredients and is considered GRAS for these uses.

Summary of Non-Clinical Performance Tests

Non-clinical performance tests were conducted according to ISO 29022:2013 using Papacarie DUO to demonstrate substantial equivalence to the predicate device, and cleaning of prepared tooth surfaces prior to bonding of restorations.

Biocompatibility of Papacarie Duo was demonstrated and the data provided in this submission according to ISO 10993-1:2018.

Conclusions

Based on the comparison of indications for use, technological characteristics and non-clinical performance testing, we believe that Papacarie Duo is substantially equivalent to the predicate device Clean and Boost and FiteBac Cavity Cleanser.