June 23, 2023

Elevate Oral Care, LLC
% Steve Pardue
Elevate Oral Care
346 Pike Road
Suite 5
West Palm Beach, Florida 33411

Re: K222323
Trade/Device Name: Black Diamond
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: PHR
Dated: June 8, 2023
Received: June 8, 2023

Dear Steve 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 (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,

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)*
K222323

Device Name
Black Diamond

Indications for Use *(Describe)*
Black Diamond is intended as 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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510(k) Summary

K222323

Submitter:

Company:	Elevate Oral Care
Street:	346 Pike Road, Suite 5
City, State Zip:	West Palm Beach, FL 33411
Country:	USA
Estab. Registration #:	3009603151
Correspondent:	Steve Pardue Managing Member
Phone:	877-866-9113
Fax:	561-244-1927
Email:	spardue@elevateoralcare.com
Date:	October 26, 2022

Name of Device

Proprietary Name:	Black Diamond™
Classification Name:	Silver Fluoride Dental Hypersensitivity Varnish 21 CFR 872.3260 as Class II device Product Code: PHR
Common Name:	Silver Fluoride Dental Hypersensitivity Varnish & Device

Predicate Devices

Primary Predicate Device	510(k)
Silver Dental Arrest	K102973
Reference Device	
Riva Star	K172047

Description

Black Diamond is a two-part liquid intended as a treatment for dentin hypersensitivity, for use in adults over the age of 21. The product does not need light cured and will provide occlusion of dentinal tubules preventing or reducing dentin hypersensitivity.

The formula has two liquid steps, each provided in an individual dropper bottle. A drop of each product is placed in a mixing well/dappen dish and applied sequentially to the tooth using a standard flock tip applicator bush such as a microbrush. The mixing pad, and applicator may or

may not be included in the product package. These are standard items in dental offices and numerous types of each will work.

Indications for Use

- Black Diamond is a two-part liquid intended as a treatment for dentin hypersensitivity, for use in patients over the age of 21.

Comparison of the Intended Use of Black Diamond to the Predicate Device

Black Diamond Indication for Use	Silver Dental Arrest
Treatment of Dental Hypersensitivity. For use in adults over the age of 21.	Treatment of Dental Hypersensitivity. For use in adults over the age of 21.

Comparison of the Intended Use of Black Diamond to the Reference Device

Black Diamond Indication for Use	Riva Star
Treatment of Dental Hypersensitivity. For use in adults over the age of 21.	Treatment of Dental Hypersensitivity. For use in adults over the age of 21.

Technological Characteristics

Black Diamond has similar composition and claims as the predicate device Silver Dental Arrest and reference product Riva Star (product codes PHR). All three devices contain silver and fluoride as the main functioning ingredient.

Black Diamond uses an aqueous solution of silver fluoride, followed by a second solution of Stannous Fluoride, a reducing agent, that causes the deposition of silver into open dentinal tubules which in turns reduces sensitivity and hydraulic conductance. This same silver deposition process is used by the predicate device as well as the reference device, both in product code PHR.

Black Diamond has been commercially available in various countries for many years with a significant safe history of use as well as a published body of literature.

Application of Black Diamond is similar to both other products in product code PHR.

Summary of Physical Tests

A hydraulic conductance test was completed showing the efficacy of Black Diamond in occlusion of dentinal tubules in comparison to the predicate device. Additionally, SEM images were taken of untreated dentin, and dentin treated with the predicate and subject device to show dentin tubule occlusion, and no other effect on healthy dentin.

It was concluded that Black Diamond is substantially equivalent to the predicate device, and reference device, and is a two-part liquid intended as a treatment for dentin hypersensitivity for use in patients over the age of 21.

Description of Safety and Substantial Equivalence

The chemical components in Black Diamond have been used extensively in dental devices and have significant toxicological profiles and safety history. Biocompatibility and Risk assessments have been completed on the product, ingredients, and combination of ingredients. Ion elution tests have been successfully completed. These facts support the compatibility of Black Diamond, and the safety of the applicant device is substantially equivalent to the predicate devices in properties, intended use and composition.

Information provided in this submission confirms the substantial equivalence to the predicate devices with common indications, and indication from the reference predicate devices. The data provided in this 510(k) submission also shows that the composition is safe for its intended use based on the biocompatibility assessment and risk assessment conducted according to ISO 10993-1 and ISO 14971.