December 6, 2022

Premier Dental Products Company
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K223632
Trade/Device Name: Premier's MultiMatch Universal Chameleon Restorative Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF
Dated: December 3, 2022
Received: December 5, 2022

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 on last page*

510(k) Number *(if known)*

K223632

Device Name

Premier's MultiMatch Universal Chameleon Restorative Composite

Indications for Use *(Describe)*

Premier's MultiMatch Universal Chameleon Restorative Composite is a nano-hybrid dental restorative intended for direct placement in all cavity classes in anterior and posterior teeth. Additional indications include repair of enamel defects, repair of provisionals, and repair of porcelain restorations, minor occlusal build-ups, core build-ups, and incisal abrasions.

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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K223632

510(k) SUMMARY

Premier Dental's MultiMatch Universal Chameleon Restorative Composite

Submitter Information

Premier Dental Products Company
1710 Romano Drive
Plymouth Meeting, PA 19462

Contact Person: Jessica Huang, Director of Quality/Regulatory

Phone: 610-239-6069
Facsimile: 610-239-6171

Date Prepared: November 29, 2022

Name of Device: Premier's MultiMatch Universal Chameleon Restorative Composite
Common or Usual Name: Tooth Shade Resin Material
Review Panel: Division of Dental and ENT Devices (DHT1B)

Classification Name: Material, Tooth Shade, Resin
Regulatory Class: 2
Product Code: EBF
Regulation Number: 21 CFR §872.3690

Predicate Devices

P1145 Dental Restorative (K162257)
Trade Name: SimpliShade

Device Description

Premier's MultiMatch Universal Chameleon Restorative Composite is a light-cured, radiopaque, resin-based nanohybrid restorative composite. It is formulated for direct placement in any type of anterior and posterior cavity form. It is intended to be used with a dental bonding agent and can be sculpted prior to curing. Once light cured, the composite can be easily finished and polished to achieve a highly esthetic and durable restoration. Available in three chameleon shades, MultiMatch can be dispensed via a unit-dose capsule or syringe to provide a restoration with an excellent visual color match to the surrounding dentition.

Intended Use / Indications for Use

Premier's MultiMatch Universal Chameleon Restorative Composite has the following indications for use:
Premier Multimatch Universal Chameleon Restorative Composite is a nano-hybrid dental restorative intended for direct placement in all cavity classes in anterior and posterior teeth.

Additional indications include repair of enamel defects, repair of provisionals and repair of porcelain restorations, minor occlusal build-ups, core build-ups, and incisal abrasions.

Summary of Technological Characteristics

Premier's MultiMatch is substantially equivalent to the predicate device, P1145 (K162257), known by Trade Name SimpliShade in terms of indications for use, composition, physical properties, and technological characteristics. Both the subject device and the predicate device are methacrylate-based resin system containing solid filler-particles to form a highly viscous paste which can be applied into a restoration preparation.

The universal dental restoratives in the predicate and subject device are both formulated with methacrylate properties of resin and fillers to undergo light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive. The composite is designed to have high mechanical strength and durability while maintaining excellent handling and esthetic characteristics.

Premier's MultiMatch formulation has been modified from the predicates to improve physical properties of mechanical strength, color stability, and reduced polymerization shrinkage.

A table comparing the key features of the subject and predicate devices is provided below.

	P1145 SimpliShade (KAVO Kerr)	**Premier's MultiMatch Universal Chameleon Restorative Composite (Subject Device)**
510K number	K162257	To be assigned
Trade Name	SimpliShade	MultiMatch
Target Users	Licensed Dental Professionals	Licensed Dental Professionals
Device Description	P1145 is a light-cured, esthetic, resin based nanohybrid dental restorative designed for direct placement in both anterior and posterior restorations. It is designed to be used after placement of a dental adhesive. Once placed, the composite can be easily sculpted to the desired shape, and after curing, can easily be finished and polished to achieve a highly esthetic restoration.	Premier's Multimatch Universal Chameleon Restorative Composite is a light-cured, radiopaque, resin-based nanohybrid restorative composite. It is formulated for direct placement in any type of anterior and posterior cavity form. It is intended to be used with a dental bonding agent and can be sculpted prior to curing. Once light cured, the composite can be easily finished and polished to achieve a highly esthetic and durable restoration. Available in three chameleon shades, MultiMatch can be dispensed via a unit-dose capsule or syringe to provide a restoration with an excellent visual color match to the surrounding dentition.

Classification Name	Tooth Shade Resin Material	Tooth Shade Resin Material
Class	2	2
Product Code	EBF	EBF
Intended Use	Dental Restorative	Dental Restorative
Indications for Use	P1145, a nano-hybrid dental restorative, is indicated for direct placement in all cavity classes in anterior and posterior teeth. Additional indication include: repair of enamel defects, repair of provisionals, repair of porcelain restorations, minor occlusal build-ups and incisal abrasions.	Premier MultiMatch Universal Chameleon Restorative Composite is a nano-hybrid dental restorative intended for direct placement in all cavity classes in anterior and posterior teeth. Additional indications include repair of enamel defects, repair of provisionals and repair of porcelain restorations, minor occlusal build-ups, core build-ups, and incisal abrasions
Intended Patient Population	Any age patient requiring restoration or repair of teeth.	Any age patient requiring restoration or repair of teeth.
Curing Mechanism	Photo-initiation	Photo-initiation
Storage	Store at Room Temperature	Store at Room Temperature
Composition	Bis-GMA TEGDMA Inorganic Filler Photo- initiator	Bis-GMA TEGDMA Inorganic Filler Photo- initiator
Material Compatibility	Meets Biocompatibility Requirements	Meets Biocompatibility Requirements
Shelf Life	Min 24 months based on accelerated data	Min 24 months based on accelerated data
Particle Size Distribution	Nanohybrid: nano and non-nano particle sizes of filler ranging from 0.04 to 6 µm	Nanohybrid: Proprietary formulation of nano and non-nano particle sizes of filler ranging from 0.7 to 5 µm
Light Intensity for Curing - Halogen	650-1000 mW/cm^2	650-1000 or Below 1000 mW/cm^2
Light Intensity for Curing – LED	>1000 mW/cm^2	1100 – 1300 or above 1000 mW/cm^2
Wavelength for Curing	450-480 nm	450-480 nm
Depth of Cure	2mm	2mm
Curing Time	Halogen – 40 seconds (dark shade) Halogen – 20 seconds (light medium and white shade) LED – 20 seconds (dark shade) LED – 10 seconds (light medium and white shade	Minimum of 20 seconds

Non Clinical Performance Data

Non-clinical performance data included testing for mechanical strength (flexural strength, compressive strength), water sorption and solubility, depth of cure, light sensitivity, radiopacity, polymerization shrinkage, volumetric wear, and color stability according to ISO 4049:2009. Working time and gloss were also performed. Biocompatibility testing was also conducted according to ISO 10993-1:2018. The data analyzed from the various tests substantiate that MultiMatch is safe and effective as the predicate P1145 (K162257).

Conclusions

Premier's Multimatch Universal Chameleon Restorative Composite is as safe and effective as the identified predicate device. Premiers MultiMatch has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. In addition, the minor technological differences between Premier's Multimatch and its predicate devices raise no new issues of safety or effectiveness. Non-Clinical Performance data demonstrate that Premier's Multimatch is as safe and effective as Kerr's P1145 (K162257), known by Trade Name SimpliShade. Thus, Premier's Multimatch is substantially equivalent.