September 22, 2021

Pulpdent Corporation
Lewis Berk
Executive Manager
80 Oakland Street
Watertown, Massachusetts 02472

Re: K210045
Trade/Device Name: Activa Presto Pack
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: May 13, 2021
Received: July 26, 2021

Dear Lewis Berk:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210045

Device Name
ACTIVA PRESTO PACK

Indications for Use *(Describe)*
ACTIVA PRESTO PACK is intended to be used by dental professionals as a dental filling material for pits, root surface cavities, and Class I, II, III, IV and V restorations. Indications include, but are not limited to, direct anterior and posterior restorations (including occlusal surfaces), core build-ups, splinting, and indirect restorations including crowns, inlays, onlays and veneers.

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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PULPDENT CORPORATION

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510(k) SUMMARY K210045

DATE OF SUBMISSION: December 22, 2020

OWNER: ***Pulpdent Corporation***

CONTACT:

Lewis W. Berk
80 Oakland Street
Watertown, Massachusetts 02472
Tel: 617 926 6666 Email: lewberk@pulpdent.com

TYPE OF SUBMISSION: Traditional 510(k)

DEVICE:

Trade Name: ***ACTIVA™ PRESTO™PACK***
Device Class: II
Classification Name: Tooth-shade resin material
FDA Product Code: EBF, 21 CFR Part 872.3690

PREDICATE DEVICES:

Pulpdent *ACTIVA™ Presto*, K153249

INTENDED USE:

ACTIVA™ PRESTO™ PACK is a light-cure, packable composite used by dental professionals as a restorative.

INDICATIONS FOR USE

ACTIVA™ PRESTO™ PACK is intended to be used as a filling material for pits, root surface cavities, and Class I, II, III, IV and V restorations. Indications include, but are not limited to, direct anterior and posterior restorations (including occlusal surfaces), core build-ups, splinting, and indirect restorations including crowns, inlays, onlays and veneers.

DESCRIPTION:

ACTIVA PRESTO™ PACK is an aesthetic, light cure material that contains calcium, phosphate, and fluoride in a durable, wear-resistant resin matrix indicated for all restorative procedures. The material is packable, sculptable, highly polishable and contains no Bisphenol A, no BisGMA and no BPA derivatives. It is available in various shades, has low solubility, low water sorption, high physical properties, and is bioactive as demonstrated within this 510(k) submission.

COMPARISON WITH PREDICATE PRODUCT:

Pulpdent PRESTO™PACK is substantially equivalent in design, composition, performance and intended use to ***ACTIVA™Presto™*** *(*K153249***).*** The predicate product has been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3690 (Code EBF).

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	Pulpdent ACTIVA™ PRESTO™ PACK	***Pulpdent ACTIVA™ PRESTO™*** **K153249**
Classification	*Recommended:* Class II Dental Device CFR 872.3690 Tooth shade resin material Product Code EBF	Class II Dental Device CFR 872.3690 Tooth shade resin material Product Code EBF
Common name	Tooth shade resin material; restorative	Tooth shade resin material; restorative
Description	Aesthetic, light cure material that contains calcium, phosphate and fluoride in a durable, wear-resistant resin matrix indicated for all restorative procedures. The material is a urethane-based resin that is packable, sculptable, highly polishable and contains no Bisphenol A, no BisGMA and no BPA derivatives.	Aesthetic, light cure material that contains calcium, phosphate and fluoride in a durable, wear-resistant resin matrix indicated for all restorative procedures. The material is a urethane-based resin that is flowable, stackable and contains no Bisphenol A, no BisGMA, and no BPA derivatives.
Intended Use	Light-cure, packable composite used by dental professionals as a restorative.	Light-cure, flowable composite used by dental professionals as a restorative.
Indications for Use	Filling material for pits, root surface cavities, and Class I, II, III, IV and V restorations. Indications include, but are not limited to, direct anterior and posterior restorations (including occlusal surfaces), core build-ups, splinting, and indirect restorations including crowns, inlays, onlays and veneers.	Universal restorative recommended as a filling material for pits, root surface cavities, and Class I, II, III, IV and V restorations.
Contraindications	Not indicated for direct placement on the exposed pulp.	Not indicated for direct placement on the exposed pulp.
Composition	*Resins*: Diurethane dimethacrylate, Bis(2-(Methacryloyloxy) Ethyl) Phosphate; *Fillers*: Barium glass, MCP (Modified calcium phosphate) *Photoinitiator*: Camphorquinone	*Resins*: Diurethane dimethacrylate, Bis(2-(Methacryloyloxy) Ethyl) Phosphate; *Fillers:* Barium glass, MCP (Modified calcium phosphate) *Photoinitiator*: Camphorquinone

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	Pulpdent ACTIVA™ PRESTO™ PACK	***Pulpdent ACTIVA™ PRESTO™*** **K153249**
Technology	When irradiated by visible light, the resins and fillers react with the photoinitiator and polymerize to form a hard composite. Designed to release calcium, phosphate and fluoride ions into the oral environment. This calcium and phosphate release is accomplished through MCP, modified calcium phosphate filler	When irradiated by visible light, the resins and fillers react with the photoinitiator and polymerize to form a hard composite. Designed to release calcium, phosphate and fluoride ions into the oral environment. This calcium and phosphate release is accomplished through MCP, modified calcium phosphate filler.
Light cure	20 ± 2 seconds in 2 mm increments	20 seconds in 2 mm increments
Dispensing system	Multi-dose, screw-type composite syringes Unit-dose capsules	Multi-dose, push syringes (1ml, 3 ml) + applicator tips Unit-dose capsules
Standards	Risk Management ISO 14971:2019 Biocompatibility ISO 10993-1:2018-08; ISO 7405:2018 Polymer-based restorative materials: ISO 4049:2019	Risk Management ISO 14971:2019 Biocompatibility ISO 10993-1:2018-08; ISO 7405:2018 Polymer-based restorative materials: ISO 4049:2019
Physical properties		
Appearance	Paste, various tooth shades	Paste, various tooth shades
Odor	Mild, characteristic	Mild, characteristic
Filler	80.0%	70.0%
Resins	20.0%	30.0%
Specific gravity	2.165 g/ml	1.820 g/ml
Depth of cure	2.42 mm	2.74 mm

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	Pulpdent ACTIVA™ PRESTO™ PACK	***Pulpdent ACTIVA™ PRESTO™* K153249**
Flexural strength	105.6 MPa	100.1 MPa
Water sorption	34.5 µg/mm^3	36.3 µg/mm^3
Solubility	7.2 µg/mm^3	4.7 µg/mm^3
Radio-opacity	2.92 mm Al	2.3 mm
Flexural modulus	7.4 ± 0.5 GPa	5.8 GPa
Deflection at break	0.54 mm	0.70 mm
Compressive strength	253 ± 25 MPa	327.4 MPa
Diametral tensile strength	47.6 ± 5.7 MPa	61 MPa
Polymerization shrinkage	2.1%	2.1%