Pulpdent Corporation
% Roger Mastrony
President
MedTek LLC
2516 Kettle Creek Court
Lincolnton, North Carolina 28092

January 5, 2018

Re: K172169
Trade/Device Name: Pulpdent (Activa) Pit and Fissure Sealant with MCP
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit And Fissure Sealant And Conditioner
Regulatory Class: Class II
Product Code: EBC, EBF
Dated: November 27, 2017
Received: December 4, 2017

Dear Roger Mastrony:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K172169

Device Name
Pulpdent Activa Pit and Fissure Sealant with MCP

Indications for Use *(Describe)*
Pulpdent's Activa Pit and Fissure Sealant with MCP is intended to seal pit and fissure depressions/faults in the enamel, in the biting surfaces of teeth. For dental professional use only.

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
K172169

DATE OF SUBMISSION: **07/11/2017, resubmitted 11-27-17.**

OWNER: ***Pulpdent Corporation***
80 Oakland Street
Watertown, MA 02472 USA

CONTACT: Roger S. Mastrony
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Lincolnton NC 28092
Tel: 1 203 640 5047 / Email: rogermastrony@gmail.com

TYPE OF SUBMISSION: Traditional 510(k).

DEVICE:

Trade Name: Pulpdent Activa Pit and Fissure Sealant with MCP
Device Class: II
Review Panel: Dental
Classification Name: Pit and Fissure Sealant
FDA Product Code: EBC, 21 CFR Part 872.3765

PREDICATE DEVICE: Pulpdent's Embrace Pit and Fissure Sealant/Dentition Integrating Material *K020287*

Please Note: Pulpdent Dentition Integrating Material was the working name for Pulpdent Embrace Pit and Fissure Sealant, before a marketing name was decided upon. It is the same formula.

REFERENCE DEVICE: Pulpdent's Activa Solo Flowable Composite with MCP *K153249*

DESCRIPTION: Activa Pit and Fissure Sealant is a light cured, flowable dental sealant material, available in a single barrel syringe. This sealant is designed with MCP (Modified Calcium Phosphate); it releases calcium, phosphate, and fluoride ions into the oral environment. It contains no Bisphenol A, no BisGMA, and no BPA derivatives.

The applicable standards and device-specific guidance documents, special controls documents, and/or requirements in a device-specific regulation, regarding device description that are applicable to the subject device, and are either referenced within this submission or used in consultation for developing this submission, include:
-ISO 4049:2009, *Polymer Based Filling Restorative and Luting Materials;*
-ANSI/ADA Specification No. 41, *Recommended Standard Practices for Biological Evaluation of Dental Materials* (Referenced for predicate device);
-ISO 10993-5:2009, *Biological Evaluation of Medical Devices-Part 5: tests for in vitro Cytotoxicity;*
-ISO 7405:1999 and 2009; and
-Guidance for Industry and FDA staff; Dental Composite Resin Devices Premarket Notification [510(k)] Submissions.

INDICATIONS FOR USE: Pulpdent's Activa Pit and Fissure Sealant with MCP is intended to seal pit and fissure depressions/faults in the enamel, in the biting surfaces of teeth. For dental professional use only.

BIOCOMPATIBILITY EVALUATION: The *subject device*, *Pulpdent Activa Pit and Fissure Sealant with MCP*, was tested with a Cytotoxicity test (ISO 10993-5: 2009). Additional chemical characterization is provided in file 012_Biocompatibility Evaluation, and a histopathology test for the predicate device, Embrace Pit and Fissure Sealant, *K020287*, is also referenced. The formula for Embrace is the same as for Activa except that Activa has MCP added. Biocompatibility of MCP in the formula is supported by presence of MCP in the reference device, Pulpdent Solo, *K153249,* which has a similar formula.

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DEVICE COMPARISON WITH PREDICATE AND REFERENCE PRODUCTS

The predicate product has been found to be substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Device under CFR 872.3765 Code EBC

	***Pulpdent* Activa Pit and Fissure Sealant with MCP**	Embrace Pit and Fissure Sealant/Pulpdent Dentition Integrating Material K020287	Pulpdent Solo Flowable Composite with MCP K153249
DESCRIPTION	Fluoride releasing, light-cured, glass filled, methacrylate resins with modified calcium phosphate	Fluoride releasing, light-cured, glass filled, methacrylate resins	Fluoride releasing, Light-cured, glass filled, methacrylate resin with modified calcium phosphate
TECHNOLOGY / MECHANISM OF ACTION	Light cured, fluoride releasing, resin sealant for filling/sealing faults in the tooth enamel	Light cured, fluoride releasing, resin sealant for filling/sealing faults in the tooth enamel	Light cured, fluoride releasing, glass filled resin for tooth restoration
INDICATIONS FOR USE	Pulpdent (Activa) Pit and Fissure Sealant with MCP is intended to seal pit and fissure depressions/ faults in the enamel, in the biting surfaces of teeth. For dental professional use only.	Pulpdent dentition integrating material is a fluoride-releasing, light-cured, resin-based material that bonds tightly to dentition and is used to fill and seal the pits and fissures in teeth.	Pulpdent Solo Flowable Composite with MCP is a fluoride, calcium, and phosphate-releasing flowable composite used by dental professionals as a restorative, base, and liner.
COMPOSITION	Diurethane dimethacrylate, Bis (2-(Methacryloyloxy) Ethyl) Phosphate, Barium glass, Silica, Sodium Fluoride, MCP (modified calcium phosphate)	Diurethane dimethacrylate, Bis (2-(Methacryloyloxy) Ethyl) Phosphate, Barium glass, Silica, Sodium Fluoride	Diurethane dimethacrylate, Bis (2-(Methacryloyloxy) Ethyl) Phosphate, Barium glass, Silica, Camphorquinone, Sodium Fluoride (optional), MCP (Modified calcium phosphate)
PHYSICAL PROPERTIES			
Appearance	Tooth shade paste/resin	Tooth shade paste/resin	tooth shade paste/resin
Specific gravity	1.39-1.42 g/mL	1.575 g/mL	1.81 ± 0.03 g/mL
pH	3.5 – 4	--	--
Compressive Strength	304 MPa (19.5)	240.0 MPa	330±47.9 MPa
Flexural Strength	98 (12) MPa	76 MPa	129±18.7 MPa
Diametral Tensile strength	49 (1.4) MPa	43.4 MPa	46.5 MPa
Water Absorption (7days)	39.2 µg/mm^3 or 2.99%	--	46.5 MPa
Water Solubility (7 days)	0.14%	0.06%	0.09%
Depth of cure	3.2 mm	3.1 mm	2.8 mm (20 sec VLC)

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Similarities

Pulpdent ACTIVA PIT AND FISSURE SEALANT and the ***predicate*** product, *PULPDENT EMBRACE PIT AND FISSURE SEALANT/Dentition Integrating Material,* both share similar technology/mechanism of action as a light curing and fluoride releasing glass filled resin. Indications for use are also the same, as a pit and fissure sealant, for depressions/faults on the tooth enamel. The chemical composition and physical properties are very similar, as described in the Device Description of this 510(k) submission.

Pulpdent ACTIVA PIT AND FISSURE SEALANT with MCP and the ***reference*** product, Pulpdent Solo Flowable Composite with MCP K153249*,* both have the same technology/mechanism of action as light curing and fluoride releasing glass filled resin with the addition of calcium and phosphate ions.

The predicate has been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3765.

Differences

Pulpdent ACTIVA PIT AND FISSURE SEALANT differs from the *predicate* product with the addition of MCP (Modified Calcium Phosphate). The subject device, predicate, and reference device have similar chemical compositions and physical properties.

Discussion of the Differences

With the addition of MCP to Pulpdent's ACTIVA PIT AND FISSURE SEALANT this sealant now has a release of calcium and phosphate ions into the oral environment, in addition to fluoride ion release seen in the predicate product. The difference is not significant because calcium and phospahte ions have a history of use in dental devices, no history of adverse reactions, as well as literature/studies that show the biocomapatability of these ions in sealing the tooth enamel.

Conclusion

Taking into account the above similarities and differences, Pulpdent ACTIVA PIT AND FISSURE SEALANT with MCP is substantially equivalent, in design, performance and indications for use, to the predicate product, *Pulpdent Embrace Pit and Fissure Sealant/Dentition Integrating Material* and to the reference product, *Pulpdent's Activa Solo Flowable Composite with MCP*.