



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 1, 2016

PULPDENT CORPORATION
c/o Roger Mastrony
MedTek LLC.
2516 Kettle Creek Court
Lincolnton, North Carolina 28092

Re: K153249

Trade/Device Name: Pulpdent Solo Flowable Composite with MCP
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth-shade resin material
Regulatory Class: Class II
Product Code: EBF
Dated: March 25, 2016
Received: March 28, 2016

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: *Pulpdent Solo Flowable Composite with MCP*

Indications for Use:

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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

PULPDENT CORPORATION

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510(k) SUMMARY

DATE OF SUBMISSION: April 1, 2016

OWNER: *Pulpdent Corporation*
80 Oakland Street
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CONTACT: Roger S. Mastrony
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Lincolnton NC 28092
Tel: 1 203 640 5047
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TYPE OF SUBMISSION: Traditional 510(k).

DEVICE:

Trade Name: *Pulpdent Solo Flowable Composite with MCP*
Device Class: II
Classification Name: Tooth-shade resin material
FDA Product Code: EBF

PREDICATE DEVICE:

Pulpdent *ACTIVA BioACTIVE-RESTORATIVE*, K130223 (Pulpdent RMGI Fill)

NOTE: Pulpdent RMGI Fill was the working name for *ACTIVA BioACTIVE-RESTORATIVE* that was used during the design and development of the product before a marketing name was decided upon. It is the same exact formula.

REFERENCE DEVICE:

Bosworth *AEGIS V with ACP*, K103585

DESCRIPTION:

Pulpdent Solo Flowable Composite with MCP is a light-cured, radiopaque, glass-filled resin with MCP (modified calcium phosphate filler) that releases calcium and phosphate ions into the oral environment and which may be formulated to release fluoride ions. ***Solo Flowable Composite with MCP*** contains no Bisphenol A, no BisGMA and no BPA derivatives. It is available in tooth shades, has low solubility, low water sorption and high physical properties.

INTENDED USE:

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.

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BIOCOMPATIBILITY EVALUATION:

Pulpdent Solo Flowable Composite with MCP was tested with a Cytotoxicity Test (ISO 10993-5:2009) and an Implantation Test (ANSI/ADA Specification 41 and ISO 7405) and found to be biocompatible.

COMPARISON WITH PREDICATE AND REFERENCE PRODUCTS:

	<i>Pulpdent Solo Flowable Composite</i> K153249 / EBF	Predicate Product: Pulpdent <i>ACTIVA BioACTIVE RESTORATIVE</i> (RMGI Fill) K130223 / EMA	Reference Product: Bosworth <i>AEGIS V with ACP</i> K103585 / EBF, EMA
DESCRIPTION / TECHNOLOGY	Light-cured, glass-filled resin with modified calcium phosphate	Dual-cure, resin-modified glass ionomer with ion releasing resins and glass	Light-cured, glass-filled resin with amorphous calcium phosphate
INTENDED USE	Dental restorative, base and liner	Dental restorative*	Dental restorative and liner
COMPOSITION	Diurethane dimethacrylate Bis (2-(Methacryloyloxy) Ethyl) Phosphate Barium glass Strontium glass Camphorquinone Sodium fluoride (optional) MCP (Modified calcium phosphate) Colorants	Diurethane dimethacrylate Bis (2-(Methacryloyloxy) Ethyl) Phosphate Barium glass Ionomer glass Polyacrylic acid/maleic acid copolymer Dual-cure chemistry Sodium fluoride Colorants.	BisGMA (Bis [4-2 (hydroxy-3-methacryloxy propyl) phenyl] propane-2) Barium glass Camphorquinone ACP (Amorphous Calcium phosphate)
PHYSICAL PROPERTIES			
Light cure set time	20 seconds	20 seconds	20 seconds
Depth of cure	2.84 mm	2.80 mm	
Appearance	Tooth-shade paste	Tooth-shade paste	Paste
Odor	Mild, characteristic	Mild, characteristic	Mild, characteristic
Specific gravity	1.810 ± 0.03 g /ml	Part A: 1.580 ± 0.02 g/mL Part B: 1.620 ± 0.02 g/mL	1.46 g/ml
Flexural strength (MPa)	129 ± 18.7	108.4 ± 14.7	
Flexural modulus GPa	8.0	----	
Compressive strength (MPa)	330 ± 47.9	270 ± 14	
Diametral tensile strength	46.5 MPa	44.4 ± 2.7	

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	<i>Pulpdent Solo Flowable Composite</i> K153249 / EBF	Predicate Product: Pulpdent <i>ACTIVA BioACTIVE RESTORATIVE</i> (RMGI Fill) K130223 / EMA	Reference Product: Bosworth <i>AEGIS V with ACP</i> K103585 / EBF, EMA
Polymerization shrinkage	2.1 %	1.7 %	
Water absorption	1.73%	1.77%	
Water solubility	0.09 %	0.25 %	
Fluoride releasing	Yes (optional)	Yes	No
Calcium releasing	Yes	Yes	Yes
Phosphate releasing	Yes	Yes	Yes

* **Note:** Although the intended use of Solo Flowable and ACTIVA RESTORATIVE are not identical, in dentistry, products are often used for multiple purposes. The inclusion of the term 'base' in the indications for use does not change the intended use of the device because placing a 'base' is one step in the process of cavity restoration. The device is placed in the same location for the purpose of filling a dental cavity and restoring function. The difference between a 'base' and a 'restorative' is the amount of the device material used.

Similarities

Pulpdent Solo Flowable Composite, ACTIVA BioACTIVE-RESTORATIVE and Bosworth Aegis V with ACP are all glass-filled resin composites that release ions into the oral environment. All the devices have the same basic structure, i.e., glass-filled resin.

Solo Flowable Composite, ACTIVA BioACTIVE-RESTORATIVE and Bosworth Aegis V with ACP are all intended to be used as dental restoratives; Solo Flowable Composite and AEGIS may also be used as a base and/or liner under cavity restorations.

Solo Flowable Composite, ACTIVA and AEGIS all release calcium and phosphate ions. Solo Flowable may be formulated to release fluoride ions like ACTIVA does.

Solo Flowable Composite and ACTIVA contain the same monomers, i.e., diurethane dimethacrylate and Bis (2-(methacryloyloxy) ethyl) phosphate.

Solo Flowable Composite and AEGIS are one-part light-cured materials. Solo Flowable Composite, ACTIVA and AEGIS all light cure in 20 seconds.

The predicate and reference medical devices have been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3690 and 872.3275.

Differences

Solo Flowable Composite and ACTIVA are formulated with urethane dimethacrylate and Bis(2-(Methacryloyloxy) Ethyl) Phosphate. Bosworth Aegis V with ACP is formulated with BisGMA (Bis [4-2 (hydroxy-3-methacryloxy propyl) phenyl] propane-2). The difference is not significant because both monomers have an established history of use in dental materials and no substantial history of adverse reactions.

ACTIVA is a two-part, resin-modified glass ionomer composite that has three setting mechanisms: light cure, self-cure resin chemistry, and acid-base glass ionomer reaction. Solo Flowable Composite and AEGIS are one-part, light-cured materials. This difference in curing chemistry is not significant because they are both used extensively in dental composites, have no substantial history of adverse events, and give the dentists a choice of curing method based on the clinical situation.

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Conclusion

Taking into account the above similarities and differences, *Pulpdent Solo Flowable Composite with MCP* is substantially equivalent in design, composition, performance and intended use to ACTIVA BioACTIVE-RESTORATIVE and Bosworth Aegis V with ACP.