DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 14,2014

Septodent-Louisville
Cora Bracho- Troconis
Director of Secintific and Regulatory Affairs
416 S. Taylor Avenue
Louisville, Co 80027

Re: K141994
Trade/Device Name: Bulk Fill Flowable Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin materal
Regulatory Class: II
Product Code: EBF
Dated: August 15, 2014
Received: August 19, 2014

Dear Ms. Bracho-Troconis:

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,

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

Section 004: Indications for Use Statement

(As Required by 21 CFR § 807.87)

510(k) Number: K141994

Device Name: **Bulk Fill Flowable Composite**

Indications for Use:

- Base under Class I and II direct restorations
- Liner under direct restorative materials
- Class III and V restorations
- Undercut Blockout
- Minimally invasive cavities (including small non stress-bearing occlusal restorations)
- Tunnel preparations
- Repair of small enamel defects
- Repair of small defects in esthetic indirect restorations
- Repair of resin and acrylic temporary materials

Prescription Use __X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Section 005: 510(k) Summary

(As Required By 21 CFR 807.92)

510(k) Applicant:

Septodont, Inc.
416 S. Taylor Ave
Louisville, Co. 80027
(303) 655-7535

Contact Person:

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Director of Scientific and Regulatory Affairs
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Date Summary was Prepared: July 14th, 2014

Trade Name: Bulk Fill Flowable Composite

Common Name: Bulk Fill Flowable Composite

Classification Name: Material, Tooth Shade, Resin

Predicate Devices:

510(k)#	Product	Manufacturer
K091635	Venus Diamond Flow	Heraeus Kulzer
K120453	Filtek Bulk Fill Flowable Restorative	3M ESPE
K123773	X-Tra Base	VOCO (GmbH)

Device Description:

The new Bulk Fill Flowable Composite manufactured by Septodont Louisville is a low viscosity, radiopaque flowable composite which sets upon exposure to a high-intensity blue light source. After polymerization, it exhibits low stress on the bond with the tooth, and it has a high polymerization conversion. This high degree of polymerization is achieved with short curing times and creates improved physical and mechanical properties.

The new Bulk Fill Flowable Composite is packaged in single dose capsules and syringes. The shades offered with Bulk Fill Flowable Composite are:

- A1, A2, A3, A3.5

Indications for Use:

- Base under Class I and II direct restorations
- Liner under direct restorative materials
- Class III and V restorations
- Undercut Blockout
- Minimally invasive cavities (including small non stress-bearing occlusal restorations)
- Tunnel preparations
- Repair of small enamel defects
- Repair of small defects in esthetic indirect restorations
- Repair of resin and acrylic temporary materials

Technological Characteristics

The new *Bulk Fill Flowable Composite* resin system consists of 3 major components. The resin system was designed using our crosslinkable proprietary monomer DDCDMA (Dimer Dicarbamate Dimethacrylate). A system has been designed using DDCDMA where EBPADMA (Ethoxylated Bisphenol "A" Dimethacrylate) is the base resin and UDMA (Urethane Dimethacrylate) is added as a minor component. This is similar to the resin system used in N'Durance, a Septodont Universal composite cleared by the FDA K072150.

This 3-component resin polymerizes using a modified initiating system The chemistry of this resin system results in low stress on the bond with the tooth and high conversion of monomers into polymers. Additionally, these resins impart a greater hydrophobicity and are less sensitive to changes in atmospheric moisture.

The filler system in the new *Bulk Fill Flowable Composite* contains Ytterbium Fluoride mono dispersed nano sized particles for dental application, Silica, as well as an acid resistant silanated Barium glass.

When irradiated by light, the methacrylate functionalities of the resins and fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.

Substantial Equivalence:

Biocompatibility:

Bulk-Fill Flowable composite was tested following ISO 10993-1:2009 and ISO 7405:2008. The conclusion of the assessment is that the product is biocompatible and safe for its intended use.

Summary of Physical Tests

This 510(k) submission includes data from bench testing to evaluate the performance of Bulk Fill Flowable Composite in comparison with its predicates. The standard utilized was ISO 4049:2009. The properties that were tested include Depth of Cure, Conversion, Compressive Strength, Flexural Strength, Diametral Tensile Strength, Microhardness, Volume Shrinkage, Shrinkage Stress, Water Absorption and Solubility.

Indications

Bulk Fill Flowable Composite has very similar indications as the claimed predicate devices Venus Diamond Flowable Composite (K091635), Filtek Bulk Fill (K120453) and X-Tra Base VOCO (K123773). Specifically, Bulk Fill Flowable Composite and Filtek Bulk Fill (K120453) are very similar in their indications, with the main difference being that Filtek Bulk Fill also includes Pit and Fissure and Core build-up indications.

Technology

The delivery and curing methods for the predicate devices are similar to that of Bulk Fill Flowable composite as well. They are all flowable composites which are applied directly to the site from a syringe or single unit dose tips. Additionally, all of these devices polymerize when irradiated by light to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.

Conclusion:

Information provided in this 510(k) submission shows that Bulk Fill Flowable Composite is substantially equivalent to the identified predicate devices in terms of intended use, indications for use, physical properties and technological characteristics. In addition to being substantially equivalent, the Bulk Fill Flowable Composite has also been determined to be biocompatible and safe for its intended use.