510(k) SUMMARY

JUL 02 2014

Premarket Notification Number K140512

This 510(k) summary information is being submitted in accordance with the requirements of 2l CFR 807.92.

510(k) Sponsor:

Juno Dentistry LP
63 Wall Street,
Madison, CT. 06443

Submitted by:

Roger Mastrony
MedTek LLC
848-1/2 Derby Avenue
Orange, CT. 06477

Date of Submission: February 21, 2014

Device Classification:

Class 2 Ref §21CFR 872.3690

Product Code:

EBF

Trade Name:

UFill Bulk Fill Posterior Flowable Composite

Common Name:

Tooth shade resin material

Device Description:

UFill Bulk Fill Posterior Flowable Composite is a light cure radiopaque posterior composite for use in the Bulk-Fill Technique. The flowable viscous material is suitable for filling layers of up to 4mm in thickness and as a cavity lining (bottom layer) for both Class I and II restorations. Placed in a unit dose needle capsule containing 0.25g of material, the device is delivered by a standard dental unit-dose tip applicator dispenser gun, and offered in a universal dentin shade that is formulated and manufactured without Bis-GMA, HEMA, or TEG-DMA.

Predicate Device(s):

3m-Filtek Bulk Fill Flowable Restorative cleared under K120453

Indications for Use:

UFill Bulk Fill Posterior Flowable Composite is indicated for use (i) in fillings with layer thicknesses up to 4mm in Class I and II cavities, (ii) in cavity lining- as a first (bottom layer) in Class I and II cavities.

Technological Characteristics:

UFill Bulk Fill Posterior Flowable Composite is a one-part light-curing, radiopaque posterior composite for use in a bulk-fill technique. The composite contains UDMA and BDDMA as resin components. A combination of silanized strontium aluminum boron silicate glass and silanized silica with a range of particle size from 0.04 to 15 µm is used as fillers. The inorganic filler loading is approximately 77 % by weight.

A dental adhesive is used to permanently bond the restoration to the tooth structure. When irradiated by light, the methacrylate functionalities of the resin 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.

Performance Testing:

Physical testing per ISO 4049-2009, Dentistry -- Polymer-based restorative materials was conducted with all criteria for success satisfied.

Safety Testing:

The device has undergone evaluation and testing in accordance with AAMI/ANSI/ISO 10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. The device was found to be suitable for body contact type and duration.

Risk Management:

The device has been evaluated in accordance with ISO 14971:2007 Medical devices - Application of risk management to medical devices. The device is safe and effective as no new risks have been identified.

Substantial Equivalence Discussion:

Substantial equivalence of the subject device, UFill Bulk Fill Posterior Composite is claimed to the predicate device, 3M – Filtek Bulk Fill cleared under K120453. The following discussion provides evidence to substantiate that claim.

Specifically,

- Indications
- Intended Use
- Basic composition of materials
- Light activated cure
- Delivery System /Method of application
- Shade
- Depth of cure
- Performance characteristics

	SUBJECT DEVICE UFill Bulk Fill Posterior Composite	**PREDICATE DEVICE** 3M – Filtek Bulk Fill (K120453)
Indications	UFill Bulk Fill Posterior Flowable Composite is indicated for use (i) in fillings with layer thicknesses up to 4mm in Class I and II cavities, (ii) in cavity lining- as a first (bottom layer) in Class I and II cavities	• Base under Class I and II direct restorations • Liner under direct restorative materials • Pit and fissure sealant • Restoration of minimally invasive cavity preparations (including small, non-stress-bearing occlusal restorations) • Class III and V restorations • Undercut blockout • Repair of small enamel defects • Repair of small defects in esthetic indirect restorations • Repair of resin and acrylic temporary materials • As a core build-up where at least half the coronal tooth structure is remaining to provide structural support for the crown

	SUBJECT DEVICE UFill Bulk Fill Posterior Composite	**PREDICATE DEVICE** 3M – Filtek Bulk Fill (K120453)
Intended Use	Fillings with Class I and II cavities, In cavity lining- as a first (bottom layer) in Class I and II cavities.	Base under Class I and II direct restorations. Liner under direct restorative materials
Basic material composition	UDMA and BDDMA as resin components Silicate glass and silanized silica fillers	UDMA and BDDMA as resin components Zirconia/silica fillers
Method of cure	Light activated	Light activated
Delivery system/Method of application	Unit dose filled tip for use in manual dispensing gun	Unit dose filled tip for use in manual dispensing gun
Shade	Universal	Universal
Depth of cure	Up to 4mm	Up to 4mm
Performance characteristics	Radiopaque Flowable Compliant to ISO 4049 Fourth edition 2009-10-01 Dentistry - Polymer-based restorative material (see Performance Testing-Bench)	Radiopaque Flowable Compliant to ISO 4049 Fourth edition 2009-10-01 Dentistry - Polymer-based restorative material

Conclusion:

There are no differences in the technological characteristics or indications for use between the subject and predicate device that raise different questions of safety & effectiveness. The subject device indications are a sub set of and are identical to those indications in the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 2, 2014

Juno Dentistry LP
C/O Mr. Roger Mastrony
MedTek LLC
848-1/2 Derby Avenue
Orange, CT 06477

Re: K140512
Trade/Device Name: UFill Bulk Fill Posterior Flowable Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: May 29, 2014
Received: June 3, 2014

Dear Mr. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

Addendum B

Indications for Use Statement

(Prescribed format)

Follows this page

Indications for Use

510(k) Number (if known): K140512

Device Name: UFill Bulk Fill Posterior Flowable Composite

Indications for Use:

UFill Bulk Fill Posterior Flowable Composite is indicated for use (i) in fillings with layer thicknesses up to 4mm in Class I and II cavities, (ii) in cavity lining- as a first (bottom layer) in Class I and II cavities

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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