

3M ESPE

MAY 08 2014

3. 510(k) Summary3M ESPE
Dental Products2510 Conway Avenue
St. Paul, MN 55144-1000**3M ESPE****510(k) Summary**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter..... 3M ESPE Dental Products
2510 Conway Avenue
St. Paul, MN 55144-1000 USA

Contact person..... Scott Erickson, RAC
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Date Summary was Prepared..... 15Apr2014

Trade Name..... Filtek™ Bulk Fill Posterior
Restorative

Common Name(s)..... Tooth shade resin material
Restorative

Recommended Classification..... 21 CFR 872.3690
Tooth shade resin material
Product Code: EBF

Predicate Devices:
Filtek™ Supreme Ultra Universal Restorative (K083610)
Metamorphosis (K091023)
Trade name: SonicFill, Sonic-Activated Bulk Fill Composite
Tetric EvoCeram Bulk Fill (K111958)

Description of Device:

3M™ ESPE™ Filtek™ Bulk Fill Posterior Restorative material is a visible-light activated, restorative composite optimized to create posterior restorations simpler and faster. This bulk fill material provides excellent strength and low wear for durability. The shades are semi-translucent and low stress curing, enabling up to a 5 mm depth-of-cure. With excellent polish retention, Filtek™ Bulk Fill Posterior Restorative is also useful for anterior restorations that call for a semi-translucent shade. All shades are radiopaque. Filtek™ Bulk Fill Posterior Restorative is offered in A1, A2, A3, B1, and C2 shades. Filtek™ Bulk Fill Posterior Restorative is applied to the tooth following use of a methacrylate-based dental adhesive, such as manufactured by 3M™ ESPE™, which permanently bonds the restoration to the tooth structure.

Filtek™ Bulk Fill Posterior Restorative is packaged in traditional syringes, for dispensing restorative on a pad outside the mouth, and single-dose capsules for dispensing restorative intraorally. The capsules are dispensed using the 3M ESPE Restorative Dispenser.

Indications for Use:

- Direct anterior and posterior restorations (including occlusal surfaces)
- Base/liner under direct restorations
- Core build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers
- Restorations of deciduous teeth
- Extended fissure sealing in molars and premolars
- Repair of defects in porcelain restorations, enamel, and temporaries

Technological Characteristics:

Filtek™ Bulk Fill Posterior Restorative is a modification of predicate device, Filtek™ Supreme Ultra Universal Restorative. The formulation was modified to create semi-translucent shades with low polymerization shrinkage stress to enable bulk placement and cure for ease of use.

The fillers used in Filtek™ Bulk Fill Posterior Restorative are a combination of a non-agglomerated/non-aggregated 20 nm silica filler, a non-agglomerated/non-aggregated 4 to 11 nm zirconia filler, an aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles), and a ytterbium trifluoride filler consisting of agglomerated 100 nm particles. The inorganic filler loading is about 76.5% by weight (58.4% by volume). The principal resins used in Filtek™ Bulk Fill Posterior Restorative are ERGP-DMA, diurethane-DMA and 1, 12-dodecane-DMA.

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:

Technological property	Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Photoinitiator system	X	X	NA ¹	X ²
Methacrylate-based resin matrix	X	X	X	X
Compatible with methacrylate-based dental adhesives	X	X	NA ¹	X
Inorganic fillers	X	X	X	X
Oxide fillers are silane treated so that they bond to the resin matrix when the restorative is cured	X	X	X ³	NA ¹
Bulk fill (up to 4 mm depth of cure)	X	-	X	X
Bulk fill (5 mm depth of cure, Class II)	X ⁴	-	X ⁴	
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.	X	X	X	X
Dispensing system: single-use capsule (intraoral) ⁵ reusable syringe (extraoral) ⁶	X X	X X	X -	X X
Recommended for load-bearing occlusal surfaces	X	X	X	X
FDA-Recognized Standards followed	Risk Management: ISO 14971 Biocomp stds ⁷ : ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 7405 Product stds ⁸ : ISO 4049 ISO 6874	Risk Management: ISO 14971 Biocomp stds ⁷ : ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 7405 Product stds ⁸ : ISO 4049	NA ¹	NA ¹

1. Not available, details not disclosed by manufacturer.
2. Product also contains a second photoinitiator.

3. Based on disclosure that product contains 3-trimethoxysilylpropyl methacrylate.
4. Similarity: In order to obtain 5 mm depth of cure for Class II restorations, product is light-cured from the occlusal surface and, after the matrix band is removed, light-cured from the buccal and lingual surfaces.

Difference: The predicate device techniques states up to a 5mm depth of cure for Class I restorations, as well, also using the multi-site light-curing process described above. For Filtek™ Bulk Fill Posterior Restorative, 4mm Depth of Cure is stated for Class I restorations, light-curing from the occlusal aspect only, as supported by ISO 4049 Depth of Cure test results. This difference does not affect the safety or efficacy of the device.

5. Restorative material is dispensed from a single-use capsule in the mouth.

Difference: The predicate device SonicFill, Sonic-Activated Bulk Fill Composite (K091023) is dispensed from the capsule using the air-driven SonicFill Handpiece, which, per the Instructions for Use “offers sonically activated delivery.”

Similarity: Filtek™ Bulk Fill Posterior Restorative and predicates Filtek™ Supreme Ultra Universal Restorative (K083610) and Tetric EvoCeram Bulk Fill (K111958) all use a traditional manual restorative dispenser (not air-driven) for dispensing capsules. In light of this similarity, the difference mentioned above does not affect the safety or efficacy of the device.

6. Restorative material is dispensed from a reusable syringe outside the mouth (e.g., onto a pad).
7. Newer versions of several biocompatibility standards were applied to Filtek™ Bulk Fill Posterior Restorative, due to time elapsed since the predicate device was evaluated. This difference is not significant because for both Filtek™ Bulk Fill Posterior Restorative and the predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610):
 - a. A Diplomat of the American Board of Toxicology assessed the safety of the product.
 - b. Standard risk assessment techniques and consideration of internationally recognized guidelines were used in the evaluation.
 - c. The conclusion of the assessment is that the device is safe for its intended use.
8. ISO 4049 data in this submission for both Filtek™ Bulk Fill Posterior Restorative and the predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610), was generated using the current version of the standard, ISO 4049:2009.

Difference: ISO 6874:2005 was not used to evaluate the predicate device, Filtek™ Supreme Ultra Universal Restorative for the 510(k) submission K083610, because it does not have a sealant indication. The only test in ISO 6874 that is applicable for a light-cure material, like Filtek™ Bulk Fill Posterior



Restorative, is Depth of Cure. This submission includes data showing both Filtek™ Bulk Fill Posterior Restorative and predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610) readily pass the ISO 6874 Depth of Cure requirement. Therefore, this difference is not significant and does not affect the safety or efficacy of the device.

Test results for the following physical properties were included in this submission: Compressive Strength, Diametral Tensile Strength, Flexural Strength, Flexural Modulus, Surface Hardness, Radiopacity, Water Sorption, Water Solubility, Volumetric Shrinkage, Wear, Depth of Cure, Cusp Deflection and Polish Retention.

Conclusion:

Filtek™ Bulk Fill Posterior Restorative is substantially equivalent to the predicate devices, Filtek™ Supreme Ultra Universal Restorative, SonicFill, Sonic-Activated Bulk Fill Composite and Tetric EvoCeram Bulk Fill in terms of intended use, indications for use, physical properties, and technological characteristics. Filtek™ Bulk Fill Posterior Restorative is substantially equivalent to the predicate device, Filtek™ Supreme Ultra Universal Restorative in terms of formulation.



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

May 8, 2014

3M ESPE Dental Products
Scott Erickson, RAC
Senior Regulatory Affairs Specialist
2510 Conway Avenue
St. Paul, MN 55144-1000

Re: K141081
Trade/Device Name: Filtek™ Bulk Fill Posterior Restorative
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: April 15, 2014
Received: April 25, 2014

Dear Mr. Erickson:

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: CDRIH 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,

Mary S. Runner -S

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

Enclosure



4. Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
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510(k) Number (if known)
K141081

Device Name
Filtek™ Bulk Fill Posterior Restorative

- Indications for Use (Describe)
- Direct anterior and posterior restorations (including occlusal surfaces)
 - Base/liner under direct restorations
 - Core build-ups
 - Splinting
 - Indirect restorations including inlays, onlays and veneers
 - Restorations of deciduous teeth
 - Extended fissure sealing in molars and premolars
 - Repair of defects in porcelain restorations, enamel, and temporaries

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)


Sheena A. Green-S
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