DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

3M ESPE Dental Products
c/o Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

November 28,2016

Re: K163207
Trade/Device Name: 3M™ Filtek™ One Bulk Fill Restorative
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: November 13, 2016
Received: November 15, 2016

Dear Mark Job:

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" (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.

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,

Susan Runner DDS, MA

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

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.

510(k) Number *(if known)*

Device Name
3M™ Filtek™ One Bulk Fill 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)*

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Appendix A
Revised Section 3 - 510(k) Summary

3. 510(k) Summary

3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144-1000

510(k) Summary

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

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

Contact person..... Scott Erickson, RAC
Senior Regulatory Affairs Specialist
Phone: (651) 736-9883
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sterickson@mmm.com

Date Summary was Prepared..... 19Oct2016

Trade Name..... 3M™ Filtek™ One Bulk Fill Restorative

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

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

Predicate Device:
Filtek™ Bulk Fill Posterior Restorative (K141081)

Description of Device:
3M™ Filtek™ One Bulk Fill Restorative, is a visible-light activated, restorative composite optimized to create fast and easy restorations. This material provides excellent strength and low wear for durability and improved esthetics. The material can be placed and cured up to 5mm deep, enabled by a stress relieving resin system and optimized optical properties. Filtek™ One Bulk Fill Restorative serves to enhance the 3M ESPE lineup of restorative materials by improving the esthetic properties of a bulk fill material to allow for broader use in both posterior and anterior restorations. Filtek™ One Bulk Fill Restorative is offered in a range of tooth-colored shades. All shades are radiopaque.

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™ One Bulk Fill Restorative is a modification of predicate device, Filtek™ Bulk Fill Posterior Restorative, also manufactured by 3M ESPE Dental Products. The formulation was modified to improve the esthetics of the cured restorative material.

The fillers 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 agglomerate 100 nm particles. The inorganic filler loading is about 76.5% by weight (58.5% by volume). Filtek™ One Bulk Fill Restorative contains AUDMA, AFM, diurethane-DMA, and 1, 12-dodecane-DMA. Filtek™ One Bulk Fill 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.

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™ One Bulk Fill Restorative	Filtek™ Bulk Fill Posterior Restorative (K141081)
Photoinitiator system	X	X
Methacrylate-based resin matrix	X	X
Compatible with methacrylate-based dental adhesives	X	X
Inorganic fillers	X	X
Oxide fillers are silane treated so that they bond to the resin matrix when the restorative is cured	X	X
Single-surface light-cure (up to 3 mm depth of cure)	X[1]	-
Single-surface light-cure (up to 4 mm depth of cure)	X	X
Multi-surface light-cure (5 mm depth of cure, Class II)	X[2]	X[2]
Multi-surface light-cure (5 mm depth of cure, Core Build-Up)	X[3]	-
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
Dispensing system: single-use capsule (intraoral)[4] reusable syringe (extraoral)[5]	X	X
Recommended for load-bearing occlusal surfaces	X	X
FDA-recognized standards followed	Risk Management: ISO 14971:2007 Biocomp stds:[6] ISO 10993-1:2009 ISO 10993-3:2003 ISO 10993-3:2014 ISO 10993-5:2009 ISO 10993-6:2007 ISO 10993-10:2010 ISO 10993-11:2006 ISO 10993-12:2012 ISO 7405:2008/ Amd1 2013 Product stds:[7] ISO 4049:2009 ISO 6874:2015	Risk Management: ISO 14971:2007 Biocomp stds:[6] ISO 10993-1:2009 ISO 10993-3:2003 ISO 10993-5:2009 ISO 10993-6:2007 ISO 10993-10:2010 ISO 10993-11:2006 ISO 10993-12:2012 ISO 7405:2008 Product stds: [7] ISO 4049:2009 ISO 6874:2005

1. Curing protocol for ≤ 3mm depth, with reduced light-cure time versus 4mm depth, is added for Filtek™ One Bulk Fill Restorative. This difference is not significant since test data shows both Filtek™ One Bulk Fill Restorative and the predicate device pass ISO 4049 3mm depth of cure requirement when using the Filtek™ One Bulk Fill Restorative light-cure recommendations.

2. 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 through tooth structure.

3. In order to obtain 5 mm depth of cure for Core Build-Up, product is light-cured from the occlusal, buccal and lingual surfaces. Core Build-Up is less challenging to light-cure than a Class II restoration (2 above), because the curing light is placed in closer proximity to the restorative material for a Core Build-Up. The multi-surface light-cure protocol provides satisfactory light-cure for Filtek™ One Bulk Fill Restorative 5mm Core Build-up and would also be expected to adequately cure predicate device 5mm Core Build-up.

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

5. Restorative material is dispensed from a reusable syringe outside the mouth (e.g., onto a pad).

6. Newer versions of two biocompatibility standards were applied to the evaluation of Filtek™ One Bulk Fill Restorative, due to time elapsed since the predicate device was evaluated. This difference is not significant because for both Filtek™ One Bulk Fill Restorative and the predicate device, Filtek™ Bulk Fill Posterior Restorative (K141081):

    a. A Diplomate 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.

7. Newer version of ISO 6874 was applied to the evaluation of Filtek™ One Bulk Fill Restorative, due to time elapsed since the predicate device was evaluated, however, this difference is not significant, since the relevant physical property requirement (Depth of Cure) did not change.

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™ One Bulk Fill Restorative is substantially equivalent to predicate device Filtek™ Bulk Fill Posterior Restorative in terms of intended use, indications for use, formulation, physical properties and technological characteristics.