3M ESPE Dental Products
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, Nw
Buffalo, Minnesota 55313

January 2, 2019

Re: K183476
Trade/Device Name: 3M Filtek Universal Restorative
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF
Dated: December 13, 2018
Received: December 17, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.01.02 09:52:12 -05'00'

For 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
3M™ Filtek™ Universal Restorative

Indications for Use *(Describe)*
- Direct anterior and posterior restorations (including occlusal surfaces)
- Core build-ups
- Splinting
- Indirect restorations including inlays, onlays, and veneers

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144-1000

510(k) Summary

This summary of 510(k) 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……..….	Lam Duong Regulatory Affairs Associate Phone: (651) 733-5945 Fax: (651) 736-1599 lduong@mmm.com
Date Summary was Prepared……	12Dec2018
Trade Name……..	3M™ Filtek™ Universal 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™ Universal Restorative, is a visible-light activated, restorative composite optimized to create esthetic anterior and posterior restorations. This material provides excellent strength and low wear for durability and improved esthetics with higher level of visual opacity. The shades are body like opacity enabling up to a 2mm depth-of-cure. The pink opaquer can be placed in 1mm thick increments. All shades are radiopaque. Filtek Universal Restorative is offered in the following shades: A1, A2, A3, A3.5, A4, B1, B2, D3, XW, and PO. The pink opaque shade option can be used to mask discolored or stained tooth structure.

Filtek™ Universal 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. Capsules may be warmed up to 70°C/158°F for one hour in a commercial warmer prior to use.

Indications for Use:
• Direct anterior and posterior restorations (including occlusal surfaces)
• Core build-ups
• Splinting
• Indirect restorations including inlays, onlays and veneers

The proposed intended use of Filtek™ Universal Restorative is the same to that of the predicate device, Filtek™ Bulk Fill Posterior Restorative. The proposed indications for Filtek™ Universal Restorative are a subset to Filtek™ Bulk Fill Posterior Restorative indications, all of which are still covered within the intended use of a dental restorative. Filtek™ Universal Restorative is a modification of predicate device with no new ingredients introduced, thus it is expected that the performance of Filtek™ Univeral Restorative and its predicate will be equivalent. The differences do not affect the safety and effectiveness of the device. Therefore, the intended use and indications of Filtek™ Universal Restorative are not significantly different to those of Filtek™ Bulk Fill Posterior Restorative.

Technological Characteristics:
Filtek Universal Restorative is a modification of predicate device, Filtek™ Bulk Fill Posterior Restorative, also manufactured by 3M ESPE Dental Products. The formulation was modified to provide a higher level of visual opacity enhancing the final esthetics of restorations.

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 (58.4% by volume). Filtek Universal Restorative contains AUDMA, AFM, diurethane-DMA, and 1, 12-dodecane-DMA. Filtek™ Universal 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™ Universal 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 2 mm depth of cure for body shades and up to 1mm depth of cure for opaque shade)[1]	X	-
Single-surface light-cure (up to 4 mm depth of cure) [2]	-	X
Multi-surface light-cure (5 mm depth of cure, Class II) [2]	-	X
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)[3] reusable syringe (extraoral)[4]	X	X
Recommended for load-bearing occlusal surfaces	X	X
FDA-recognized standards followed	Risk Management: ISO 14971:2007 Biocomp stds: ISO 10993-1:2009 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:[5] ISO 4049:2009	Risk Management: ISO 14971:2007 Biocomp stds: ISO 10993-1:2009 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: [5] ISO 4049:2009 ISO 6874:2005

1. Curing protocol for ≤ 2mm depth, with reduced light-cure time versus 4mm depth, was not included for Filtek™ Bulk Fill Posterior Restorative 510(k) submission. This difference is not significant since test data shows both Filtek™ Universal Restorative and the predicate device pass ISO 4049 depth of cure requirement when using the Filtek™ Universal Restorative light-cure recommendations.

2. The increased visual opacity due to changes made in pigment levels from the predicate device, Filtek™ Bulk Fill Posterior Restorative, makes Filtek™ Universal Restorative a traditional restorative, requiring 2mm incremental placement. The slightly lower pigment loading used in Filtek™ Bulk Fill Posterior Restorative makes it a bulk fill restorative and can be cured in bulk up to 4mm depth from a single surface and up to 5mm depth from three surfaces (occlusal, buccal and lingual). This change in physical property does not affect the safety or efficacy of the device when used as labeled. This difference is not significant since test data shows both Filtek™ Universal Restorative and the predicate device pass ISO 4049 depth of cure requirement.

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

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

5. ISO 6874:2005 was not used to evaluate Filtek™ Universal Restorative because the product does not have a sealant indication. The only test in ISO 6874 that is applicable for a light-cure material such as the predicate device, Filtek™ Bulk Fill Posterior Restorative (K141081), is Depth of Cure. The Depth of Cure test is also included in ISO 4049:2009. This submission includes data showing both Filtek™ Universal Restorative and predicate device, Filtek™ Bulk Fill Posterior Restorative, readily pass the ISO 4049 Depth of Cure requirement. Therefore, this difference is not significant and does not affect the safety or efficacy of the device.

Test results for stability testing, biocompatibility testing, and 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:

3M™ Filtek™ Universal 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.