June 13, 2022

3M Company ESPE Dental Products
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K221695
Trade/Device Name: 3M Filtek Supreme Flowable Restorative
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF, EBC
Dated: June 9, 2022
Received: June 10, 2022

Dear Prithul Bom:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K221695

Device Name

3M™ Filtek™ Supreme Flowable Restorative

Indications for Use *(Describe)*

- Direct Restoration of all cavity classes (I-V)
- Base/liner under direct restorations
- Repair of small defects in esthetic indirect restorations
- Repair of resin and acrylic temporary materials
- Pit and fissure sealant

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.

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3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144-1000

510(k) Summary

3M™ Filtek™ Supreme Flowable Restorative

3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144-1000

510(k) Summary K221695

This 510(k) summary is submitted in accordance with the requirements of 21 CFR 872.3690.

510(k) Submitter…… 3M Company
ESPE Dental Products
2510 Conway Avenue
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Establishment Registration No.: 3005174370

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Submission Date……11 May 2022

Proprietary Trade Name…….3M™ Filtek™

Device Name…….…….…Supreme Flowable Restorative

Common Name……. Tooth Shade Resin Material

Classification Name…… Tooth Shade Resin Material

Regulation Number……..21 CFR 872.3690

Product Code…….…….…….EBF

Classification Panel…….….Dental Products Panel 76

Classification…….…….Medical Device, Class II

Predicate Devices:

Primary Predicate:

3M™ ESPE™ Filtek™ Supreme Ultra Flowable Restorative (K100235)

Secondary Predicate:

Tetric EvoCeram (K042819)

3M ESPE 2510 Conway Avenue
Dental Products St. Paul, MN 55144-1000

Description of Device:

Filtek™ Supreme Flowable Restorative is a low viscosity, visible-light activated, radiopaque, flowable nanocomposite. It is available in a variety of tooth-colored shades.

Filtek™ Supreme Flowable Restorative contains Bis GMA, TEGDMA, and Procrylat K resins. The fillers are a combination of an Ytterbium Fluoride filler, a non-agglomerated/non-aggregated surface-modified silica filler, and a surface-modified aggregated zirconia/silica cluster filler. The aggregate has an average cluster particle size of 0.6 to 10 microns. The inorganic filler loading is approximately 65% by weight (46% by volume).

Filtek Supreme Flowable Restorative is applied to the tooth following the use of a methacrylate-based dental adhesive such as manufactured by 3M, which permanently bonds 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. The product is available in both syringe and capsule delivery systems.

Indications for Use:

- Direct Restoration of all cavity classes (I-V)
- Base/liner under direct restorations
- Repair of small defects in esthetic indirect restorations
- Repair of resin and acrylic temporary materials
- Pit and fissure sealant

The purpose of this submission is to update the Indications for Use for this product to include all cavity classes of direct restorations and to summarize other changes that did not require 510(k) submission, such as a minimal change to the syringe design and extension of shelf-life to 36 months.

Technological Characteristics:

Filtek™ Supreme Flowable Restorative is identical to the primary predicate Filtek™ Supreme Ultra Flowable Restorative (K10023) in terms of formulation, design, performance features, and biocompatibility as well as manufacturing processes. The change in the name of the product is for simplification purposes only.

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Dental Products St. Paul, MN 55144-1000

Substantial equivalence

As the primary goal of this submission is to update the Indications for Use to include all cavity classes, the information provided in this 510(k) submission shows that the product is substantially equivalent to the primary predicate, 3M Filtek Supreme Ultra Flowable Restorative (K100235), and the secondary predicate, Tetric EvoCeram (K042819), a device that has been cleared for all cavity classifications.

	Applicant Device	**Primary Predicate**	**Secondary Predicate**
Trade Name	Filtek™ Supreme Flowable Restorative	Filtek™ Supreme Ultra Flowable Restorative (K100235)	Tetric EvoCeram® (K042819)
Product Category	Tooth Shade Resin Material	Tooth Shade Resin Material	Tooth Shade Resin Material
Intended Use	Composite Resin Device for Dental Restorations	same	same
Indications for Use	• Direct restoration of all cavity classes (I-V) • Base/liner under direct restorations • Repair of small defects in esthetic indirect restorations •Repair of resin and acrylic temporary materials • Pit and fissure sealant	• Class III and V restorations • Restoration of minimally invasive cavity preparations (including small, non-stress-bearing occlusal restorations) • Base/liner under direct restorations • Repair of small defects in esthetic indirect restorations •Repair of resin and acrylic temporary materials • Pit and fissure sealant • Undercut blockout	• Anterior Restoration (Class III, IV) • Class V restorations (cervical caries, root erosion, wedge-shaped defects) •Restoration of the posterior regions (Class I and II) •Veneering of discolored anterior teeth • Splinting of mobile teeth • Repair of composite and ceramic veneers

No new questions of safety and effectiveness are raised with these additional Indications for Use. The changes to the Indications for Use as compared to the primary predicate are explained below. The decision to remove these indications is based on a desire to simplify the Indications for Use.

"Restoration of minimally invasive cavity preparation" is considered a smaller subset of Class I-V restorations and does not require a separate indication for use.

"Undercut blockout" is a procedure used for both direct and indirect restoration. It is considered a part of tooth prepping for any class of direct restoration.

The decision not to add additional information to each class of restoration (unlike the secondary predicate device) was based on the well-understood definition of the classes of restorations, which is part of the dentist's training.

The difference between the shades offered by the secondary predicate and Filtek Supreme Flowable Restorative does not affect the functionality of Filtek Supreme Flowable restorative; it can be used safely and effectively for all the proposed indications.

The safety and efficacy of 3M Filtek Supreme Flowable Restorative remain unchanged from the primary predicate, Filtek Supreme Ultra Flowable Restorative, since Filtek Filtek Supreme Flowable Restorative is identical to the primary predicate device in terms of formulation, design, performance features, and biocompatibility as well as manufacturing processes.

The additional minor changes (including updated delivery tip design and addition of the narrower gage tip) do not affect the safety and efficacy of the product.

Testing was undertaken to substantiate the use of the Filtek Supreme Flowable Restorative for Classes I, II, and IV restorations, the new indication being added when compared to the secondary predicate device. This 510(k) submission includes data from *in vitro* testing per FDA Guidance "*Dental Composite Resin Devices – Premarket Notification [510(K)]"* issued on October 26, 2005, ISO 4049:2019 *Dentistry – Polymer-based Restorative Materials*, and ISO 6874:2015 *Dentistry - Polymer-based pit and fissure sealants.* To evaluate the performance of Filtek Supreme Flowable Restorative for these new indications, comparative testing results for the following physical properties were included in this submission:

- Flexural Strength
- Compressive Strength
- Surface hardness (Barcol)
- Elastic Modulus/Flexural Modulus
- Radiopacity
- Water Sorption
- Water Solubility
- Fracture toughness to demonstrate chip resistance

This testing was conducted with the existing flowable restorative material (Filtek Supreme Ultra Flowable Restorative), the primary predicate device) in an updated syringe delivery device. The results submitted in the 510(k) demonstrated material strength equivalent or superior as compared to the secondary predicate. All results met the requirements of the ISO standards 4049 and 6874. In particular, the acceptability of the test results in comparison with the secondary predicate establishes the adequacy of Filtek Supreme Flowable Restorative to be used in all classes of cavity restorations.

The biocompatibility of the applicant device product was also assessed, and it was confirmed that no additional biocompatibility testing was required to support the submission because the formulation of Filtek Supreme Flowable Restorative is identical to the primary predicate device since the clearance of its original 510(k) and continues to meet biocompatibility requirements.

Nanotechnology assessment and risk evaluation of the formulation in Filtek Supreme Flowable Restorative and Filtek Supreme Ultra Flowable Restorative did not identify any specific health hazards attributable to the nanomaterials present in the product.

Based on stability studies, the established shelf life for Filtek Supreme Flowable restorative is 36 months at ambient temperature. The stated shelf-life is predictive of both syringe and capsule shelf-life stability.

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.