



August 31, 2022

Kerr Corporation  
Haiyan Wei  
Senior Regulatory Affairs Specialist  
1889 W Mission Blvd  
Pomona, California 91766

Re: K221255

Trade/Device Name: SimpliShade Bulk Fill, SimpliShade Bulk Fill Flow  
Regulation Number: 21 CFR 872.3690  
Regulation Name: Tooth Shade Resin Material  
Regulatory Class: Class II  
Product Code: EBF  
Dated: August 5, 2022  
Received: August 5, 2022

Dear Haiyan Wei:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For 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

## Indications for Use

510(k) Number (if known)  
K221255

Device Name  
SimpliShade Bulk Fill, SimpliShade Bulk Fill Flow

### Indications for Use (Describe)

The SimpliShade Bulk Fill is indicated for:

- Direct placement of anterior and posterior restorations.
- Core build-ups.
- Repair of defects in restorations.

The SimpliShade Bulk Fill Flow is indicated for:

- Base/liner under Class I and Class II direct restorations.
- Pit and fissure sealant.
- Restoration of small cavities.
- Class III and V restorations.
- Blocking out undercuts.
- Small core build-ups.
- Repair of resin and acrylic provisional restorations.

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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## K221255 - 510(k) Summary

for

SimpliShade™ Bulk Fill, SimpliShade™ Bulk Fill Flow

### 1. Submitter Information:

Kerr Corporation  
1889 W Mission Blvd  
Pomona, CA 91766  
USA

Contact Person: Haiyan Wei  
Telephone Number: (714) 516-7710  
Email: haiyan.wei@kavokerr.com

Date Prepared: June 27, 2022

### 2. Device Name:

Proprietary Name: SimpliShade™ Bulk Fill, SimpliShade™ Bulk Fill Flow  
Manufacturer: Kerr Corporation  
Common Name: Tooth Shade Resin Material Restorative  
Classification Name: Tooth Shade Resin Material  
CFR Number: 872.3690  
Device Class: II  
Product Code: EBF

### 3. Predicate Device (Primary):

Proprietary Name: Filtek™ One Bulk Fill Restorative (K163207)  
Manufacturer: 3M ESPE Dental Products  
Common Name: Tooth Shade Resin Material Restorative  
Classification Name: Tooth Shade Resin Material  
CFR Number: 872.3690  
Device Class: II  
Product Code: EBF

### Predicate Device #2:

Proprietary Name: Filtek™ Bulk Fill Flowable Restorative (K120453)  
Manufacturer: 3M ESPE Dental Products  
Common Name: Tooth Shade Resin Material  
Classification Name: Tooth Shade Resin Material  
CFR Number: 872.3690  
Device Class: II  
Product Code: EBF

### 4. Device Description:

SimpliShade™ Bulk Fill Composite is offered in two types of viscosities: the high viscosity formula will be branded as SimpliShade™ Bulk Fill; the low viscosity formula will be branded as SimpliShade™ Bulk Fill Flow.

### SimpliShade™ Bulk Fill:

SimpliShade Bulk Fill is an intra-oral, light-cured, esthetic, resin-based nanohybrid dental restorative that is designed for the placement of direct restorations. SimpliShade Bulk Fill is designed to be used after placement of a dental adhesive, such as a product from the Kerr OptiBond™ family.

SimpliShade Bulk Fill is available in Unidose™ compules and syringe delivery systems that are suitable for occlusal surfaces. The product offers allows a technique in which a cavity up to 5 mm in depth can be filled and cured in a single increment. SimpliShade Bulk Fill is offered in one universal shade to optically blend with a range of VITA™ shade guide equivalents. This composite can be polished with a wide variety of polishing discs, rubber cups, and brushes.

**SimpliShade™ Bulk Fill Flow:**

SimpliShade Bulk Fill Flow is an intra-oral, light-cured, esthetic, resin-based nanohybrid dental restorative that is designed to be used as a base or liner in Class I and II restorations and must be overlaid with a composite resin to replace the occlusal surfaces. It is also suitable to be used on non-occlusal-contact surfaces, such as pit and fissures, core build-ups and Class III and V restorations.

SimpliShade Bulk Fill Flow is available in Unidose™ compules and syringe delivery systems. The product allows a technique in which a cavity up to 4 mm in depth can be filled and cured in a single increment. SimpliShade Bulk Fill Flow is offered in one universal shade to optically blend with a range of VITA™ shade guide equivalents. Once light cured, the composite can be finished and polished using conventional finishing and polishing instruments.

5. **Principle of Operation / Mechanism of Action:**

**SimpliShade™ Bulk Fill:**

SimpliShade Bulk Fill is a high viscosity resin-based nano-hybrid dental restorative that can be light-cured. It is designed to be used after placement of a dental adhesive. Once the bonding procedure is completed, a liner using a low viscosity flowable composite may optionally be placed and light cured according to the manufacturer's instructions prior to placing SimpliShade Bulk Fill. SimpliShade Bulk Fill is intended to be cured by exposure to light waves with a minimum light intensity of 650 mW/cm<sup>2</sup> and a light wavelength output within the 400-520 nm range, in incremental layers up to 5 mm. The handling behavior of the material is achieved through the addition of a proprietary rheology modifier as well as an optimized balance of the concentration of the filler system with the resin concentration. 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.

**SimpliShade™ Bulk Fill Flow:**

SimpliShade Bulk Fill Flow is a low viscosity resin-based nano-hybrid dental restorative that can be light-cured. It is designed to be used after placement of a dental adhesive. Once the bonding procedure is completed, a layer of SimpliShade Bulk Fill Flow is placed directly onto the prepared site along the axial and gingival margins. With a brushing action, the material can flow into the marginal interfaces and recesses of the preparation in up to 4mm increments; SimpliShade Bulk Fill Flow is intended to be cured by exposure to light waves with a minimum light intensity of 650 mW/cm<sup>2</sup> and a light wavelength output within the 400-520 nm range. The handling behavior of the material is achieved through the addition of a proprietary rheology modifier as well as an optimized balance of the concentration of the filler system with the resin concentration. 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.

6. **Indications for Use:**



SimpliShade™ Bulk Fill is indicated for:

- Direct placement of anterior and posterior restorations.
- Core build-ups.
- Repair of defects in restorations.

SimpliShade™ Bulk Fill Flow is indicated for:

- Base/liner under direct restorations.
- Pit and fissure sealant.
- Restoration of small cavities.
- Class III and V restorations.
- Blocking out undercuts.
- Small core build-ups.
- Repair of resin and acrylic provisional restorations.

**7. Description of Substantial Equivalence:**

The similarities between the SimpliShade™ Bulk Fill, SimpliShade™ Bulk Fill Flow (Subject Device) and the Primary Predicate Device Filtek™ One Bulk Fill Restorative (K163207), Predicate Device #2 Filtek™ Bulk Fill Flowable Restorative (K120453), include the Regulatory Classification, Intended Use of the device, Indications for Use, Mode of Action, Device description, and Clinical condition of use. Furthermore, Technological Characteristics and Performance testing including Biocompatibility testing are similar.

There are no major differences but only minor differences between the SimpliShade™ Bulk Fill, SimpliShade™ Bulk Fill Flow (Subject Device) and the Primary Predicate Device Filtek™ One Bulk Fill Restorative (K163207), Predicate Device #2 Filtek™ Bulk Fill Flowable Restorative (K120453). The formulation composition slightly varies and performance test results have slightly different values; however, these minor differences have no impact on the device performances which demonstrate subject devices are substantially equivalent as predicate devices.

Table 1 below compares the SimpliShade™ Bulk Fill, SimpliShade™ Bulk Fill Flow (Subject Devices) and the Primary Predicate Device Filtek™ One Bulk Fill Restorative (K163207), Predicate Device #2 Filtek™ Bulk Fill Flowable Restorative (K120453) with respect to intended use, technological characteristics and performance testing.

**Table 1:** Device Comparison Table

| Descriptive Information          | Subject Device 1<br>SimpliShade™ Bulk Fill<br>(K221255) | Subject Device 2<br>SimpliShade™ Bulk Fill Flow<br>(K221255) | Predicate Device (Primary)<br>Filtek™ One Bulk Fill Restorative<br>(K163207) | Predicate Device #2<br>Filtek™ Bulk Fill Flowable Restorative<br>(K120453) | Comparison          |
|----------------------------------|---|--|--|--|---------------------|
| Manufacturer                     | Kerr Corporation  | Kerr Corporation   | 3M ESPE Dental Products  | 3M ESPE Dental Products  | N/A                 |
| <b>Regulatory Classification</b> |   |  |  |  |                     |
| Regulation #                     | 21 CFR 872.3690   | 21 CFR 872.3690  | 21 CFR 872.3690  | 21 CFR 872.3690  | Same as Predicates. |
| Regulation Title                 | Tooth Shade Resin Material                              | Tooth Shade Resin Material                                   | Tooth Shade Resin Material   | Tooth Shade Resin Material   | Same as Predicates. |

| <b>Regulation Class</b>                 | Class II   | Class II   | Class II   | Class II   | Same as Predicates.   |
|---|--|--|--|--|---|
| <b>Product Code</b>                     | EBF  | EBF  | EBF  | EBF  | Same as Predicates.   |
| <b>Indications for Use/Intended Use</b> |  |  |  |  |   |
| <b>Intended Use</b>                     | Material, Tooth Shade, Resin   | Material, Tooth Shade, Resin   | Material, Tooth Shade, Resin   | Material, Tooth Shade, Resin   | Same as Predicates.   |
| <b>Indications for Use</b>              | <ol style="list-style-type: none"> <li>1. Direct placement of anterior and posterior restorations.</li> <li>2. Core build-ups.</li> <li>3. Repair of defects in restorations.</li> </ol> | <ol style="list-style-type: none"> <li>1. Base/liner under direct restorations.</li> <li>2. Pit and fissure sealant.</li> <li>3. Restoration of small cavities.</li> <li>4. Class III and V restorations.</li> <li>5. Blocking out undercuts.</li> <li>6. Small core build-ups.</li> <li>7. Repair of resin and acrylic provisional restorations.</li> </ol> | <ol style="list-style-type: none"> <li>1. Direct anterior and posterior restorations (including occlusal surfaces).</li> <li>2. Base/liner under direct restorations.</li> <li>3. Core build-ups.</li> <li>4. Splinting.</li> <li>5. Indirect restorations including inlays, onlays and veneers.</li> <li>6. Restorations of deciduous teeth.</li> <li>7. Extended fissure sealing in molars and premolars.</li> <li>8. Repair of defects in porcelain restorations, enamel, and temporaries.</li> </ol> | <ol style="list-style-type: none"> <li>1. Base under Class I and II direct restorations.</li> <li>2. Liner under direct restorative materials.</li> <li>3. Pit and fissure sealant.</li> <li>4. Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations).</li> <li>5. Class III and V restorations.</li> <li>6. Undercut blockout.</li> <li>7. Repair of small enamel defects.</li> <li>8. Repair of small defects in esthetic indirect restorations.</li> <li>9. Repair of resin and acrylic temporary materials.</li> <li>10. As a core build-up where at least half the coronal tooth structure is remaining to provide structural support for the crown.</li> </ol> | Same Indication for Use as Predicate Devices and expressed through similar choice of wording. |
| <b>Technological Characteristics</b>    |  |  |  |  |   |
| <b>Clinical condition of use</b>        | Dental clinics or similar healthcare settings.   | Dental clinics or similar healthcare settings.   | Dental clinics or similar healthcare settings.   | Dental clinics or similar healthcare settings.   | Same as Predicate Devices.  |
| <b>Anatomical location of use</b>       | Oral, teeth  | Oral, teeth  | Oral, teeth  | Oral, teeth  | Same as Predicate Devices.  |
| <b>Principles of Operation</b>          | Tooth shade resin-based dental restorative that can be light-cured by  | Tooth shade resin-based dental restorative that can be light-cured by  | Tooth shade resin-based dental restorative that can be light-cured by  | Tooth shade resin-based dental restorative that can be light-cured by  | Same as Predicate Devices.  |

|  |  |  |  |  |                               |
|--|--|--|--|--|-------------------------------|
|  | photo polymerization.                                    | photo polymerization.                                    | photo polymerization.                                    | photo polymerization.                                    |                               |
| <b>Storage</b>   | Store at room temperature 2-28°C (36-82°F).              | Store at room temperature 2-28°C (36-82°F).              | Store at room temperature 2-27°C.                        | Store at room temperature 2-27°C.                        | Similar to Predicate devices. |
| <b>Compatible with methacrylate-based dental adhesives</b> | Yes  | Yes  | Yes  | Yes  | Same as Predicate Devices.    |
| <b>Recommended for load-bearing occlusal surfaces</b>      | Yes  | No   | Yes  | No   | Same as Predicate Devices.    |
| <b>Primary Packaging</b>                                   | Syringe and Capsule                                      | Syringe and Capsule                                      | Syringe and Capsule                                      | Syringe and Capsule                                      | Same as Predicate Devices.    |
| <b>Material Composition</b>                                | Methacrylate resins, Photo-initiators, Inorganic fillers | Methacrylate resins, Photo-initiators, Inorganic fillers | Methacrylate resins, Photo-initiators, Inorganic fillers | Methacrylate resins, Photo-initiators, Inorganic fillers | Similar to Predicate devices. |
| <b>Containing Inorganic Fillers</b>                        | Yes  | Yes  | Yes  | Yes  | Same as Predicate Devices.    |
| <b>Primary Filler particle size range</b>                  | 40 nm – 0.4 µm   | 40 nm – 0.1 µm   | 4 nm – 100 nm  | 10 nm – 5.0 µm   | Similar to Predicate devices. |
| <b>Curing Mechanism</b>                                    | Photo-initiation   | Photo-initiation   | Photo-initiation   | Photo-initiation   | Same as Predicate Devices.    |
| <b>Intensity (mW/cm<sup>2</sup>) for curing</b>            | ≥ 650 mW/cm <sup>2</sup>                                 | ≥ 650 mW/cm <sup>2</sup>                                 | ≥ 550 mW/cm <sup>2</sup>                                 | ≥ 550 mW/cm <sup>2</sup>                                 | Similar to Predicate devices. |
| <b>Wavelength (nm) for curing</b>                          | 400 - 520 nm   | 400 - 520 nm   | 400 – 500 nm   | 400 – 500 nm   | Similar to Predicate Devices. |
| <b>Curing Time (sec)</b>                                   | 20 sec (≥ 650 mW/cm <sup>2</sup> )                       | 20 sec (≥ 650 mW/cm <sup>2</sup> )                       | At least 20 sec (≥ 550 mW/cm <sup>2</sup> )              | 20 sec (≥ 550 mW/cm <sup>2</sup> )                       | Similar to Predicate Devices. |
| <b>Depth of Cure (mm)</b>                                  | Up to 5mm  | Up to 4mm  | Up to 5mm  | Up to 4mm  | Similar to Predicate Devices. |
| <b>Compressive Strength (MPa)</b>                          | Meet the criteria per internal standard                  | Meet the criteria per internal standard                  | Meet the criteria per internal standard                  | Meet the criteria per internal standard                  | Similar to Predicate Devices. |



|   |   |   |   |  |                               |
|---|---|---|---|--|-------------------------------|
| <b>Internal standard &gt;260 Mpa</b>                        |   |   |   |  |                               |
| <b>Rockwell Hardness (RHN) Internal Standard &gt;65 RHN</b> | Meet the criteria per internal standard   | Meet the criteria per internal standard   | Meet the criteria per internal standard   | Meet the criteria per internal standard  | Similar to Predicate Devices. |
| <b>Flexural Strength (Mpa)</b>                              | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement  | Similar to Predicate Devices. |
| <b>Radio-opacity (mm of Al)</b>                             | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement  | Similar to Predicate Devices. |
| <b>Water Sorption (µg/mm³)</b>                              | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement  | Similar to Predicate Devices. |
| <b>Water Solubility (µg/mm³)</b>                            | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement  | Similar to Predicate Devices. |
| <b>Sensitivity to ambient light</b>                         | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement  | Same as Predicate Devices.    |
| <b>Color Stability</b>                                      | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement   | Conform to ISO 4049 requirement  | Same as Predicate Devices.    |
| <b>Performance Testing</b>                                  |   |   |   |  |                               |
| <b>Biocompatibility</b>                                     | ISO 10993-1:2018<br>ISO 10993-3:2014<br>ISO 10993-5:2009<br>ISO 10993-6:2016<br>ISO 10993 10:2021<br>ISO 10993-11:2017<br>ISO 10993-12:2021<br>ISO 10993-23:2021<br>ISO 7405:2018 | ISO 10993-1:2018<br>ISO 10993-3:2014<br>ISO 10993-5:2009<br>ISO 10993-6:2016<br>ISO 10993-10:2010<br>ISO 10993-11:2017<br>ISO 10993-12:2021<br>ISO 10993-23:2021<br>ISO 7405:2018 | ISO 10993-1:2009<br>ISO 10993-3:2014<br>ISO 10993-5:2009<br>ISO 10993-6:2007<br>ISO 10993-10:2010<br>ISO 10993-11:2006<br>ISO 10993-12:2012<br>ISO 7405:2008 /AMD1 2013 | ISO 10993-1:2009<br>ISO 10993-3:2003<br>ISO 10993-5:2009<br>ISO 10993-6:2007<br>ISO 10993-10:2010<br>ISO 10993-11:2006<br>ISO 10993-12:2012<br>ISO 7405:2008 | Similar to Predicate devices. |
| <b>Dentistry - Polymer-based restorative materials</b>      | ISO 4049:2019   | ISO 4049:2019   | ISO 4049:2009   | ISO 4049:2009  | Similar to Predicate devices. |

8. **Non-Clinical Test Data:**



Performance bench tests according to ISO 4049 for Dental Polymer-Based Restorative Materials have been conducted to determine conformance in regards of flexural strength, sensitivity to light, water sorption, water solubility, depth of cure, radio-opacity, and color stability etc. Additional tests such as compressive strength, diametral tensile strength, rockwell hardness, surface hardness, and volumetric shrinkage, wear, and shrinkage stress have been performed to compare the subject devices and predicate devices. The data from these tests demonstrate that the subject devices SimpliShade Bulk Fill and SimpliShade Bulk Fill Flow are substantially equivalent to the predicate devices 3M Filtek One Bulk Fill Restorative and 3M Filtek Bulk Fill Flowable Restorative.

9. **Clinical Performance Data:**

Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on the subject devices.

10. **Conclusion as to Substantial Equivalence:**

Based on a comparison of intended use, indications, material composition, technological characteristics, principle of operation, features and performance data, the SimpliShade™ Bulk Fill and SimpliShade™ Bulk Fill Flow are deemed to be substantially equivalent to the predicate devices.