August 31, 2026

Guilin Kevin Peter Technology Co., Ltd.
Qian Zhang
RA Registration
North Side Of Linsu Rd., Lingui Town, Lingui Dist.
Guilin, Guangxi 541100
CHINA

Re: K261695
Trade/Device Name: Flowable Restorative Material (KP-Flow LF, KP-Flow MF, KP-Flow HF)
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBC
Dated: May 22, 2026
Received: May 22, 2026

Dear Qian Zhang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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Respiratory, ENT, and Dental Devices
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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.

510(k) Number *(if known)*
K261695

Device Name
Flowable Restorative Material (KP-Flow LF, KP-Flow MF, KP-Flow HF)

Indications for Use *(Describe)*
Intended purpose: This product can be used for direct restoration of anterior and posterior.

Indications:
- 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.

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

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桂林凯文彼德科技有限公司
Guilin Kevin Peter Technology Co., Ltd.

510(k) Summary

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

1 Submitter's Information

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Contact: Zhang Qian

Designated Submission Correspondent

Mrs. Zhang Qian
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Email: rcd05@kvpeter.com

Date of Preparation: Sep.25,2024

2 Device Information

Trade Name: KP-Flow Flowable Restorative Material
Device Name: Flowable Restorative Material
Common Name: Tooth Shade Resin Material
Classification Name: Material, Tooth Shade, Resin
Model: KP-Flow LF, KP-Flow MF, KP-Flow HF

3 Classification

Production code: EBF
Regulation number: 21 CFR 872.3690
Classification: Class II
Panel: Dental

4 Identification of Predicate Device

Predicate Device:

510(k) Number: K221695

Device Name: Filtek™ Supreme Flowable Restorative

Manufacturer: 3M COMPANY ESPE Dental Products

5 Indication for Use Statement

Intended purpose: This product can be used for direct restoration of anterior and posterior.

Indications:

- 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

6 Device Description

KP-Flow Flowable Restorative Material is a kind of composite resin filling material that can be cured by visible light for the filling and restoration of anterior teeth and posterior teeth.

The product is available in a variety of colors, such as dentin color, tooth color, enamel color, transparent color and other colors. All shades are radiopaque. It is a class 2 product whose use requires the energy to be applied intra-orally. It is packaged in syringes.

7 Summary of Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the FDA-Recognized Standard ISO 4049:2019 Dentistry - Polymer-based restorative materials and FDA guidance “Guidance for Industry and FDA Staff Dental Composite Resin Devices-Premarket Notification [510(k)]Submissions Document, issued on October 26, 2005”.

In-vitro bench tests were performed on the KP-Flow Flowable Restorative Material including the items listed in the table below. The test results indicated that the KP-Flow Flowable Restorative Material meets the pass criteria and supports substantial equivalence when compared to the predicate device on physical properties.

Items	Acceptable criteria	Conclusion
ISO 4049: 2019 5.2.7 Sensitivity to ambient light, Class 2 materials	The material shall remain physically homogeneous.	Meet the criteria per ISO 4049
ISO 4049: 2019 5.2.8 Depth of cure, Class 2 materials ISO 6874:2015 , 4.2.3 Depth of cure, Class 2 Sealant	All restorative materials: ≥1.5 mm	Meet the criteria per ISO 4049 , ISO 6874
ISO 4049: 2019 5.2.9 Flexural strength and Flexural Modulus	The flexural strength shall be equal to or greater than 50 MPa	Meet the criteria per ISO 4049
ISO 4049: 2019 5.2.10 Water sorption and solubility	1) The water sorption shall be ≤ 40μg/mm^3 2) The solubility shall be shall be ≤ 7.5μg/mm^3	Meet the criteria per ISO 4049
ISO 4049: 2019 5.3 Shade of restorative materials	When the material is assessed in accordance with 7.13 and ISO 7491, the shade of the set material shall closely match that of the manufacturer's shade guide. The set material shall be evenly pigmented when viewed without magnification	Meet the criteria per ISO 4049

ISO 4049: 2019 5.4 Colour stability after irradiation and water sorption	The set material shall be evenly pigmented when viewed without magnification	Meet the criteria per ISO 4049
ISO 4049: 2019 Radio-opacity	The radio-opacity shall be equal to or greater than that of the same thickness of aluminium (1 mm of material)	Meet the criteria per ISO 4049
FDA guidance Elastic modulus	The test results of the subject device's elastic modulus showed no significant difference from those of the predicate device	Meet the requirements of FDA guidance
FDA guidance Surface hardness	The test results of the subject device's surface hardness showed no significant difference from those of the predicate device	Meet the requirements of FDA guidance
FDA guidance Compressive strength	The test results of the subject device's compressive strength showed no significant difference from those of the predicate device	Meet the requirements of FDA guidance

Biocompatibility Testing:

Biocompatibility tests were performed fully following the ISO 10993-1 and ISO 7405 standards. The test items include:

- In Vitro Cytotoxicity Test - ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Sensitization - ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Intracutaneous Reactivity Test - ISO 10993-23:2021 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Acute systemic Toxicity Test - ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Subchronic systemic Toxicity Test - ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Bacterial Reverse Mutation Test - ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- Mouse Lymphoma Cells(TK) Gene Mutation Test- ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- In vitro Mammalian Chromosome Aberration Test - ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.

8 Summary of Clinical Testing

Clinical testing was not required for this submission.

9 Technological Characteristics and Substantial Equivalence

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 1 General Device Characteristics Comparison Table

Item	Subject device	Predicate device K 221695
Product Name	KP-Flow Flowable Restorative Material	Filtek™ Supreme Flowable Restorative
Product Code	EBF	EBF

Regulation No.	21 CFR 872.3690	21 CFR 872.3690
Class	II	II
Intended Use	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	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.
Prescription Use	Yes	Yes
Composition of Materials	BisEMA, BisGMA, UDMA, TEGDMA, barium silanized glass, zirconia/silica cluster filler, silica filler, pigments, photo-initiators and stabilizers. KP-Flow LF: The inorganic filler loading is about 65%, particle size is between 0.6μm and 10 μm. KP-Flow MF: The inorganic filler loading is about 69% by wt for the Bulk Fill shades and 63.5% by wt for all other shades.The particle size of inorganic fillers is between 0.6μm and 10 μm. KP-Flow HF: The inorganic filler loading is about 53%, particle size is between 0.6μm and 10 μm.	BisGMA, TEGDMA and Procrylat resins. The fillers are a combination of ytterbiumn trifluoride filler with a range of particles sizes from 0.1 to 5.0 microns, a non-agglomerated/non-aggregated surface modified 20nm silica filler, a non-agglomerated/non-aggregated surface modified 75nm silica filler, and a surface modified aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles). 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).

Curing method	Light cure	Light cure
Delivery form	Syringe	Capsules and Syringes.
Physical Properties	The subject device and the predicate device have substantially equivalent physical properties including compressive strength, flexural strength, Diametral Tensile Strength， Flexural Modulus, depth of cure , surface hardness, radio-opacity, water sorption and solubility as they all meet the criteria per ISO 4049 and FDA guidance "Guidance for Industry and FDA Staff Dental Composite Resin Devices-Premarket Notification[510(k)] Submissions Document issued on October 26,2005".	
FDA-Recognized Standards	ISO 4049, ISO 6874 , ISO 7405, ISO 10993-1 , ISO 10993-3, ISO 10993-5, ISO 10993-10, ISO 10993-23	ISO 4049, ISO 6874 , ISO 7405, ISO 10993-1, ISO 10993-3,ISO 10993-5, ISO 10993-10, ISO 10993-23

The subject device has same intended use, incorporates the same fundamental technology, and has same indications for use as the predicate device,both products are intended for direct anterior and posterior restorations.

The technological characteristics of the subject device are very similar to those of the predicate device, Physical property comparison data support substantial equivalence of the subject device when compared to the predicate device.

10 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the differences between the subject device and the predicat device are insignificant in terms of substantial equivalence. The subject device is substantially equivalent to the predicate device.