Ivoclar Vivadent, AG
% Lori Aleshin
Director of Quality & Regulatory Affairs
Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228

March 14, 2019

Re: K183380
Trade/Device Name: Tetric® PowerFill
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: December 21, 2018
Received: December 26, 2018

Dear Lori Aleshin:

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: 2019.03.14 09:38:49 -04'00'

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

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)*
K183380

Device Name
Tetric® PowerFill

Indications for Use *(Describe)*
Conventional application (Light intensity ≤2,000 mW/cm2):
- Restorations in the posterior region (Class I and II, including the replacement of individual cusps)
- Class V restorations (cervical caries, root erosion, wedge-shaped defects)
- Reconstructive build-ups
- Restoration of deciduous teeth

Light-curing using the 3sCure mode of Bluephase® PowerCure (Light Intensity 3,050 mW/cm2):
- Restorations in the posterior region of permanent dentition (Class I and II, including the replacement of individual cusps) when light-cured from the occlusal aspect

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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510(K) SUMMARY
K183380

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Date Prepared: December 4, 2018

Proprietary Name: **Tetric® PowerFill**

Classification Name: Material, Tooth Shade, Resin (872.3690)
(Classification Code EBF)

Predicate Device: Tetric EvoCeram Bulk Fill (K111958) by Ivoclar Vivadent, AG

Device Description: **Tetric® PowerFill** is a light-curing radiopaque resin-based composite for the direct restorative treatment in posterior teeth. Tetric PowerFill cures with light in the wavelength range of 400-500 nm and can be applied in layers of up to 4 mm. The monomer matrix is composed of dimethacrylates (20–21 wt%). The fillers contain barium glass, ytterbium trifluoride, mixed oxide and copolymer (79–80 wt%). Additives, initiators, stabilizers and pigments are additional ingredients (< 1.0 wt%). While using the 3sCure mode of Bluephase Power-Cure (3,050mW/cm2), the material can be cured within 3 seconds. The material is available in syringes and cavifils.

Tetric® PowerFill composite material is available in Universal shades: IVA, IVB, IVW

Indications for Use:

Conventional application (Light intensity ≤2,000 mW/cm2):
- Restorations in the posterior region (Class I and II, including the replacement of individual cusps)
- Class V restorations (cervical caries, root erosion, wedge-shaped defects)
- Reconstructive build-ups
- Restoration of deciduous teeth

Light-curing using the 3sCure mode of Bluephase® PowerCure (Light Intensity 3,050 mW/cm2):
- Restorations in the posterior region of permanent dentition (Class I and II, including the replacement of individual cusps) when light-cured from the occlusal aspect

Comparison to Predicate: The primary predicate devices to which Tetric® PowerFill has been compared is Ivoclar Vivadent, AG Tetric EvoCeram Bulk Fill (K111958).

Device	Ivoclar Vivadent AG: Tetric EvoCeram Bulk Fill (K111958)	Ivoclar Vivadent: Tetric® PowerFill
Indications for Use	- Restoration of Deciduous teeth - Restorations in the posterior region (Class I and II) - Class V restorations (cervical caries, root erosion,wedge-shaped defects) - Extended fissure sealing in molars and premolars	**Conventional application (Light intensity ≤ 2,000 mW/cm2):** - Restorations in the posterior region (Class I and II, including the replacement of individual cusps) - Class V restorations (cervical caries, root erosion, wedge-shaped defects) - Reconstructive build-ups - Restoration of deciduous teeth **Light-curing using the 3sCure mode of Bluephase® PowerCure (Light Intensity 3,050 mW/cm2):** - Restorations in the posterior region of permanent dentition (Class I and II, including the replacement of individual cusps) when light-cured from the occlusal aspect
Precaution Measures/ Contraindications/ Processing restrictions/ Side effects	**The placement of Tetric EvoCeram Bulk Fill restorations is contraindicated:** - If a dry working field cannot be established, or the stipulated working technique cannot be applied. - If a patient is known to be allergic to any of the ingredients of Tetric EvoCeram Bulk Fill. **Side effects** In individual cases, components of Tetric EvoCeram Bulk Fill may lead to sensitization. Tetric EvoCeram Bulk Fill should not be used in such cases. To avoid possible irritation of the pulp, areas close to the pulp should be protected with a suitable pulp/dentin protector (selectively apply a calcium hydroxide-based preparation in areas close to the pulp and cover it with a suitable cavity liner). **Warning** Avoid contact of unpolymerized Tetric EvoCeram Bulk Fill with skin, mucous membrane and eyes. Unpolymerized Tetric EvoCeram Bulk Fill may have a slight irritating effect and may lead to a sensitization against methacrylates. Commercial medical gloves do not	**The placement of Tetric PowerFill restorations is contraindicated** - If a dry working field cannot be established, or the stipulated working procedures cannot be applied. - If a patient is known to be allergic to any of the ingredients of Tetric PowerFill **Side effects** In individual cases, components of Tetric PowerFill may lead to sensitization. Tetric PowerFill should not be used in such cases. To avoid possible irritation of the pulp, areas close to the pulp should be protected with a suitable pulp/dentin protector (selectively apply a calcium hydroxide-based preparation in areas close to the pulp and cover with suitable cavity liner). **Warning** Unpolymerized Tetric PowerFill should not come in contact with skin, mucous membrane and eyes. Unpolymerized Tetric PowerFill may have a slight irritating effect and may lead to a sensitization against methacrylates.

	provide protection against the sensitizing effect of methacrylates.	Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates. **Safety notes** – Do not place light in direct contact with unprotected gingiva, mucous membrane or skin. – The 3sCure curing mode must not be used in case of caries profunda and very deep cavities.
Summary of Indications, Precaution Measures/ Contraindications/ Processing restrictions/ Side effects	The new device Tetric PowerFill lacks the indication "Extended fissure sealing in molars and premolars" in contrast to the predicate device and includes the indication "reconstructive build-ups". Extended fissure sealing is a feature that has established itself for flowable composites and is therefore not intended for Tetric PowerFill. All composites that can be used for direct occlusion fillings can also be uses as reconstructive buildup materials as they have the physical characteristics therefore. According to this the indication has been added to the new device Tetric PowerFill. The contraindications are the same for both devices. Side effects and warnings are the same. The safety notes are an addition for the new device because of the curing time of 3 seconds with a polymerization light with a light intensity of 3,050 mW/cm$_2$.	
Technology	Tetric EvoCeram Bulk Fill is a light-curing, radiopaque nano-hybrid composite for direct restorations in posterior teeth. Tetric EvoCeram Bulk Fill cures with light in the wavelength range of 400-500 nm and can be applied in layers of up to 4 mm.	Tetric PowerFill is a light-curing radiopaque composite for the direct restorative treatment in posterior teeth. Tetric PowerFill cures with light in the wavelength range of 400-500 nm and can be applied in layers of up to 4mm. While using the 3sCure mode of Bluephase Power- Cure (3,050mW/cm$_2$), the material can be cured within 3 seconds.
Summary of Technology	The working principle for both devices is substantially equivalent: both products are light-curing resin-based dental restorative materials. Tetric PowerFill can be cured with a dental curing light with a light intensity ≤ 2,000 mW/cm$_2$ like its predicate. The innovation of the new device Tetric PowerFill is that the device can be cured within 3 seconds using a curing light with a light intensity of 3,050 mW/cm$_2$ for class I and II restorations in the posterior region.	
Delivery forms/dosage	Syringes and cavifils	Syringes and cavifils
Summary of Delivery forms/dosage	No difference.	

Storage Conditions	48 months at 2-28 °C / 36-82 °F	48 months at 2-28 °C / 36-82 °F
Summary of Storage Conditions	No difference.	
Principles of Operation	**Step-by-step:** - Shade determination - Isolation - Cavity preparation - Pulp protection /Base - Apply matrix /interdental wedge - Conditioning / Application of the bonding agent - Application of Tetric Evoceram Bulk Fill - Finishing / Checking the occlusion / Polishing	**Step-by-step:** - Shade determination - Isolation - Cavity preparation - Pulp protection/Base (3sCure mode is mentioned) - Apply matrix / interdental wedge - Conditioning/Application of the bonding agent - Application of Tetric PowerFill - Finishing /Checking the occlusion / Polishing
Summary Principles of operation	The slight differences in the application are explained by the 3sCure mode of a curing light with a light Intensity of 3,050 mW/cm2. The principles of operation for the predicate and the new device are substantially equivalent.	
Finished Device Specification	Applicable standard: ISO 4049:2009-Dentistry – Polymer-based restorative materials Applicable FDA Guidance: No information	Applicable standard: ISO 4049:2009-Dentistry- Polymer-based restorative materials Dental Composite Resin Devices – Premarket Notification [510(k)] Submission
Sterilization	Not applicable. No sterilization recommendation.	Not applicable. No sterilization recommendation.
Single use	Consumable material	Consumable material
Summary of Finished Device Specification	Tetric® PowerFill fulfils the relevant standard and follows the relevant Guidance.	
Summary of Performance Specification	The performance of the new device Tetric PowerFill is substantially equivalent to the predicate device.	

Substantial equivalence to the predicate:

Both devices, the predicate Tetric EvoCeram Bulk Fill and the new device Tetric PowerFill are light-curing resin-based dental restorative composite devices. The physical properties are the same for both devices, the composition has been slightly changed for the new device.

Differences:
The slight differences in the application are explained by the 3sCure mode of a curing light with a light Intensity of 3,050 mW/cm2.
The principles of operation for the predicate and the new device are substantially equivalent.

Non-clinical performance testing:
Bench testing was performed to test the physical properties included in the Finished Device Specification for the subject device including: flexural strength, curing depth, sensitivity to light, wavelength for curing, water sorption and water solubility and radiopacity according to ISO 4049:2009. The subject device was tested in direct comparison to the predicate device and the results of the bench testing show the products to be substantially equivalent.

Biocompatibility:
The subject device was also evaluated for Biocompatibility according to ISO 10993-1:2009, ISO 7405:2008 and ISO 14971:2012. The following testing was conducted on the subject device: Cytotoxicity according to EN ISO 7405:2008 + A1:2013; ISO 10993-5:2009 and Genotoxicity according to EN ISO10993-3:2014 and the device was found to be non-cytotoxic and non-genotoxic. In addition to testing, additional criteria for biocompatibility including irritation, delayed-type hypersensitivity/Sensitization, systemic toxicity, implantation, and pulp and dentine usage were also evaluated based on a review of the literature and the evaluation concluded the benefits provided by the subject device will exceed any potential biocompatibility risks. This supports a finding of substantial equivalence due to the biocompatibility of the predicate device.

The Subject device was not tested or evaluated for pulp capping, endodontic usage, biodegradation, EMC, Software, animal and sterility validation as they are not applicable.

The results of the Biocompatibility Assessment for Tetric PowerFill is substantially equivalent to the results of the Biocompatibility Assessment for the predicate device Tetric EvoCeram Bulk Fill.

Conclusion:

The new device Tetric PowerFill is substantially equivalent to the predicate device Tetric EvoCeram Bulk Fill.