Ivoclar Vivadent AG
% Donna Hartnett
Director QA/Regulatory Affairs
Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228

June7, 2018

Re: K173573
Trade/Device Name: Tetric® CAD
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: May 3, 2018
Received: May 8, 2018

Dear Donna Hartnett:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 -S

forTina 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)*
K173573

Device Name
Tetric® CAD

Indications for Use *(Describe)*
Tetric® CAD is intended for:
- Veneers
- Inalys
- Onlays (e.g. occlusal veneers, partial crowns)
- Crowns in the anterior and posterior region

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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510(K) SUMMARY

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Date Prepared: June 5, 2018

Proprietary Name: Tetric® CAD

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

Predicate Device: Cerasmart (K133824) by GC America, Inc.

Device Description: Tetric® CAD is a composite block for the fabrication of esthetic permanent inlays, onlays, veneers and crowns in the anterior and posterior region. Fabrication of the dental restoration is performed at the dentist's office in a compatible milling machine. The blocks are composed of cross-linked dimethacrylate and inorganic fillers. In the processing technique, the restoration is polished and seated after milling in the CAD/CAM system. The blocks are attached to a metal mandrel, the geometry of such is compatible with a milling machine, e.g. Cerec/InLab (Sirona), PlanMill (PlanMeca) or Programill One (Ivoclar Vivadent).

Tetric® CAD composite blocks are available in the translucency levels MT (5 shades – A1, A2, A3, A3.5, BL) and HT (4 shades 0 A1, A2, A3, A3.5), and in the sizes I12 and C14.

Indications for Use:

Tetric® CAD is intended for:

- Veneers
- Inalys
- Onlays (e.g. occlusal veneers, partial crowns)
- Crowns in the anterior and posterior region

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Comparison to Predicate: The primary predicate devices to which Tetric® CAD has been compared is GC America's Cerasmart (K133824).

Device	GC America: Cerasmart (K133824)	Ivoclar Vivadent: Tetric® CAD (K173573)
Indications for Use	The product is indicated for inlays, onlays, veneers and full crown restorations, including crowns on implants.	Tetric® CAD is intended for: - Veneers - Inlays - Onlays (e.g. occlusal veneers, partial crowns) - Crowns in the anterior and posterior region
Precaution Measures/ Contraindications/ Processing restrictions/ Side effects	In rare cases this product may cause sensitivity in some people. If such reactions are experienced, discontinue the use of product and consult a physician. Personal protective equipment such as gloves, face masks and safety eyewear should always be worn.	Contraindications: - Bridge constructions - Conventional and self-adhesive cementation - Temporary cementation - Patients with severely reduced residual dentition - Any other use not listed in the indications Failure to observe the following restrictions may compromise the results achieved with Tetric® CAD: - Falling short of the required minimum layer thicknesses - Milling the blocks in a non-compatible CAD/CAM system - Deviations from the recommended luting protocol If a patient is known to be allergic to any of the ingredients of Tetric® CAD, the material should not be used. Do not inhale the composite resin dust during finishing. Use suction equipment and wear a dust mask
Summary of Indications, Precaution Measures/ Contraindications/ Processing restrictions/ Side effects	The precautions, processing restrictions and contraindications are described in more detail for Tetric® CAD, but in total the indications and contraindications are substantially equivalent.	
Technology	Cerasmart is a pre-cured composite block for milling CAD/CAM indirect restorations. The milled device is used for the restorations of both anterior and posterior teeth.	Tetric® CAD is a composite block for the fabrication of permanent inlays, onlays, veneers and crowns in the anterior and posterior region. In this processing technique, the restoration is polished and incorporated immediately after milling in the CAD/CAM system.
Summary of Technology	The devices are similar, there is a minor difference in the wording.	
Delivery forms/dosage	The blocks are available in 3 sizes (12, 14, 14L) in 33 shades (Translucency HT, LT and one Bleach shade).	The blocks are available in the translucency levels MT and HT, in 5 and 4 shades respectively, and in the sizes I12 and C14.

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Summary of Delivery forms/dosage	The predicate device is available in 3 sizes, one more than Tetric® CAD (14L is not available for Tetric® CAD). Additionally the predicate device offers 33 shades (Translucency HT, LT and a Bleach shade), Tetric® CAD offers 5 shades for MT and 4 shades for HT. Even though less shades are available the dentist can still meet the aesthetic demands of the patient.	
Storage Conditions	Storage at room temperature (4 – 25°C/39.2 – 77.0°F), away from direct sunlight and high humidity; Shelf life: 5 years from date of manufacture	Storage conditions: 2 – 28°C/36 – 82°F, avoid sunlight Shelf life: 36 months
Summary of Storage Conditions	The recommended shelf life is shorter for the new product, as less data is currently available.	
Principles of Operation	Step by Step: -Preparation Design, shade selection -Scanning and Milling -Finishing and polishing -Characterization -Pre-Treatment -Cementation -Maintenance and repair	Step by Step: - Preparation, shade determination - Intraoral imaging, CAD/CAM process - Polishing - Characterization - Preparing for cementation - Cementation - Checking the articulation/occlusion, polishing - Aftercare
Summary Principles of operation	There are minor differences in the wording between the predicate and the new product Tetric® CAD, but these are not significant and the principle of the operation is substantially equivalent.	
Summary Chemical Composition	Both products are pre-cured composite blocks with differences in composition. Tetric® CAD has evaluated biocompatibility according to ISO 10993- 1:2009.	
Finished Device Specification	Applicable standard: No information Applicable FDA Guidance: No information	EN 1641:2009 – Dentistry – Medical devices for dentistry - Materials Dental Composite Resin Devices – Premarket Notification [510(k)] Submission
Sensitivity to light	Not relevant – industrially cured	Not relevant – industrially cured
Color stability	Not relevant – industrially cured	Not relevant – industrially cured
Flexural Strength	Brochure: 238 MPa	Typical mean value (IFU): 272 MPa
Sterilization	Not applicable. No sterilization recommendation.	Not applicable. No sterilization recommendation.
Single use	Consumable material	Consumable material
Summary of Finished Device Specification	Tetric® CAD fulfils the relevant standard and follows the relevant Guidance.	
Summary of Performance Specification	The value for flexural strength of Cerasmart (GC`s brochure) correlates with Ivoclar Vivadent`s Tetric® CAD.	

Substantial equivalence to the predicate:

The subject and the predicate device are pre-cured composite blocks for milling CAD/CAM restorations. Thus, the devices have the same function, have similar principles of operation and a similar chemical composition. The forgoing comparison supports that the subject device is substantially equivalent to the predicate device.

Differences:

The recommended storage temperature is marginally different (2-28 °C) compared to 4-25 °C for the predicate device. This is not substantial and is due to company policy.
The shelf life is shorter (36 months) compared to 5 years for the predicate device. This is not substantial and is due to ongoing real-time testing.

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The chemical composition is not fully published for the predicate device and therefore it is assumed there is some difference in ingredients, although the published data shows both products to be 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: water sorption and water solubility according to ISO 10477:2004 and flexural strength according to ISO 6872:2015. 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 +AC:2010. 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 10993-3:2014 and the device was found to be non-cytotoxic and non-genotoxic.

Conclusion: The data show that Tetric® CAD is substantially equivalent to the predicate device.