April 21, 2022

Kulzer, LLC
Marc Henn
Director QA/RA
4315 S. Lafayette Blvd
South Bend, Indiana 46614

Re: K220605
Trade/Device Name: Venus Bulk Flow ONE
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: February 22, 2022
Received: March 2, 2022

Dear Marc Henn:

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.

510(k) Number *(if known)*
K220605

Device Name
Venus Bulk Flow ONE

Indications for Use *(Describe)*
Extended fissure sealing
First-layer lining for class I and class II cavities
Class I, II, III and V direct restorations
Repair of direct and indirect restorations in combination with a suitable adhesive
Splinting loosened teeth resulting from trauma or periodontal associated events

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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SUBJECT: Venus Bulk Flow ONE Special 510(k) Summary- K220605

Date: February 15, 2022

Owner: Kulzer, LLC
4315 S. Lafayette Blvd.
South Bend, IN 46614

PRIMARY CORRESPONDENT: Marc Henn, Director of QA/RA
Phone (574) 261-2555
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ADDITIONAL CORRESPONDENT: David Vincent, Director of QA/RA
Phone (574) 298-5424
Email David.Vincent@kulzer-dental.com

Trade Name (80792**):** Venus Bulk Flow ONE
Common Name: Restorative Material **Product**
Code: 76 E BF
Classification Name (21 CFR 872.3690)**:** Material, Tooth Shade Resin **807.92(a)3 Legally marketed device of which equivalence is claimed**: VenusDiamond Flow (K091635)

[807.92(a)(4)] Description of Device:

Venus Bulk Flow ONE is a light curing, radio-opaque nano-hybrid composite.

The uncured dental composite is introduced into the oral cavity to be applied and cured to the tooth structure or restoration pre-treated by the dentist, thus achieving the clinicalbenefit.

Venus Bulk Flow ONE is used for extended fissure sealing, first-layer lining for class I and class II cavities, Class I, II, III and V direct restorations, repair of direct and indirectrestorations in combination with a suitable adhesive, splinting loosened teeth resulting from trauma or periodontal associated events.

Product Image:

Specifications:

Parameter	**Required Specification**
5.2.7 sensitivityto dental OP light	> 60 s
5.2.8 depth of cure	> 1,5 mm
5.2.9 flexural strength	> 80 MPa
5.2.10 water sorption	< 40 µg/mm³
5.2.10 water solubility	< 7,5 µg/mm³
5.4. colour stability	no more than slight change in color
5.5 radio-opacity	> 100%-Al and SD < 50%, if claimed

[807.92(a)(5)] Intended Use:

Venus Bulk Flow ONE is used for extended fissure sealing, first-layer lining for class I and class II cavities, Class I, II, III and V direct restorations, repair of direct and indirectrestorations in combination with a suitable adhesive, splinting loosened teeth resulting from trauma or periodontal associated events.

The predicate device (K091635) is restricted to areas not subjected to masticatory forces. This is the primary difference between the subject device Venus Bulk Flow ONE and the predicate device which is Venus Diamond Flow (K091635). The intended population for use is dental patients needing restorations. The expanded indication of not being limited to areas that are notsubjected to masticatory surfaces allows for more broad use of this product in dental restorations for said indications. Internal studies per ISO 4049 yielded results that demonstrate this product is appropriate for use in those areas safely.

[807.92(a)(6)] Technological Characteristics:

The basic fundamental scientific technology of the subject device Venus Bulk Flow ONE versusthe predicate device Venus Diamond Flow (K091635) are identical. The chemistries are identical. Conditions of use, time of patient contact, physical properties, biocompatibility, tissue contact, patient population, users are all identical.

The differences are different composite amount in the packaging, depth of cure, and less restrictive indications for use. The subject device Venus Bulk Flow ONE syringe contains 2g of material while the predicate device Venus Diamond Flow (K091635) contains 1.8g. This has no effect on safety or efficacy. The depth of cure for the subject device Venus Bulk Flow ONE is 4mm while for the predicate device Venus Diamond Flow (K091635) it is 2mm. The 4mm curing depth is achieved by modification of the opacity (color) only. This has no effect on safety or efficacy. The remaining difference which is a less restrictive indications for use due to the removal of the restriction not to use on masticatory surfaces also has no effect on safety and efficacy. The predicate device Venus Diamond Flow (K091635) same as subject device Venus Bulk Flow ONE was tested perISO 4049 and met the requirements therein. Since both devices meet the ISO 4049 requirements, both could have had this restriction removed. At the time Venus DiamondFlow (K091635) was cleared and released for sale, it simply was not thought of.

[807.92(b)(1)]: Non-clinical bench testing:

The following testing was performed:

- light sensitivity
- depth of cure
- flexural strength
- water sorption
- water solubility
- color stability
- radio-opacity

In all cases, results were either equal or better than the predicate Venus Diamond Flow(K091635) and exceeded specifications as required by ISO 4049:2019. With these results in mind, the subject device Venus Bulk Flow ONE is better than or equivalent tothe predicate device Venus Diamond Flow (K091635) in all cases.

[807.92(b)(2)] Clinical Performance Data:

A formal clinical trial was not performed.

Venus Bulk Flow ONE is the latest product development of Kulzer's dental flowable composites. It is based on a modification of Venus Diamond Flow, marketed since 2009. According to the performed Equivalence Evaluation, the devices Venus Bulk FlowONE and Venus Diamond Flow can be considered equal. Venus Bulk Flow ONE was developed to further simplify and accelerate the process of direct composite restorationswith good aesthetics.

The translucency of Venus Bulk Flow ONE is reduced to the possible minimum, while still allowing 4 mm of curing depth. In this way, the bulk-fill technique is possible without compromise in aesthetics. Both Venus Diamond Flow and Venus Bulk Flow ONE meet the performance requirements of ISO 4049:2019. There is no clinically significant difference in the safety and clinical performance of the devices Venus Diamond Flow and Venus Bulk Flow ONE. Therefore, the current clinical evaluation "Dental Composites" remains valid and applies to Venus Bulk Flow ONE. This statement verifies that Venus Bulk Flow ONE, when used under the conditions andfor the purposes intended, will perform only with known and foreseeable risks and side effects (inclusively from foreseeable misuse). No new risks or other previously unknownsafety issues or side effects were identified.

807.92(b)(3) Conclusions from Non-clinical and Clinical Tests:

Based on the above non-clinical and clinical evaluation data/tests, the subject device Venus Bulk Flow ONE is as safe and effective as the predicate device Venus DiamondFlow(K091635).

807.92(d) Information reasonably deemed necessary by FDA:

Any additional information reasonably deemed necessary by the FDA will be provided ina timely a fashion as possible.

807.92(e) Indications for Use:

	Subject Device Venus Bulk Flow ONE (K220605)	**Predicate Device Venus Diamond Flow (K091635)**
Indication for Use	• Extended fissure sealing • First-layer lining for class I and II cavities • Class-I, -II, -III and -V direct restorations • Repair of direct and indirect restorations in combination with a suitable adhesive Splinting loosened teeth resulting from trauma or periodontal associated events	• Enlarged fissure sealing •Cavity lining – as the first layer for Class I and II cavities •Class V fillings •Minimally invasive Class I and II fillings in areas not subjected to masticatory forces •Minimally invasive Class III fillings • Small repairs of direct and indirect restorations combined with a suitable bonding agent Interlocking of loosened teeth