March 11, 2026

Kulzer, LLC
% Dave Yungvirt
CEO
Third Party Review Group, LLC
7 Giralda Farms, Suite 120a
Madison, New Jersey 07940

Re: K260783
Trade/Device Name: Venus Diamond; Venus Diamond Flow; Venus Pearl; Venus Bulk Flow One
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF, EBC, LBH
Dated: March 9, 2026
Received: March 10, 2026

Dear Dave Yungvirt:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260783

Device Name
Venus Bulk Flow One

Indications for Use *(Describe)*
- Class I, II, III, IV and V direct restorations
- First-layer lining for class I and II cavities
- Repair of direct and indirect restorations in combination with a suitable adhesive
- Splinting of teeth
- Extended fissure sealing
- Composite attachments for aligner treatment
- Fixation of retainers

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260783

Device Name
Venus Diamond Flow

Indications for Use *(Describe)*
- Enlarged fissure sealing
- Cavity lining – as the first layer for Class I and II cavities
- Class I, II, III, IV and V direct restorations
- Small repairs of direct and indirect restorations combined with a suitable bonding agent
- Splinting of teeth
- Composite attachments for aligner treatment
- Fixation of retainers

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260783

Device Name
Venus Diamond

Indications for Use *(Describe)*

- Direct restorations of all cavity classes
- Direct composite veneers
- Shape corrections of teeth (i.e. diastemas, congenital defects in teeth, etc.)
- Splinting of teeth
- Restoration of primary teeth
- Core build-up
- Repairs of porcelain, composite (in combination with an adequate repair-system)
- Composite attachments for aligner treatment
- Fixation of retainers

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260783

Device Name
Venus Pearl

Indications for Use *(Describe)*

- Direct restorations of all cavity classes
- Direct composite veneers
- Shape corrections of teeth (i.e. diastemas, congenital defects in teeth, etc.)
- Splinting of teeth
- Restoration of primary teeth
- Core build-up
- Repairs of porcelain, composite (in combination with an adequate repair-system)
- Composite attachments for aligner treatment
- Fixation of retainers

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)

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510(k) Summary – Traditional 510(k)

Date Prepared: 03/09/2026

Contact Details

Applicant Name: Kulzer LLC

Applicant Address: 4315 S Lafayette Blvd South Bend, IN 46614 United States

Applicant Contact Telephone: (574) 299-5467

Applicant Contact: Mr. Aiden Lane

Applicant Contact Email: aiden.lane@kulzer-dental.com

Device Name and Classification (Bundled Submission):

Device Trade Name:

- Venus Diamond
- Venus Diamond Flow
- Venus Pearl
- Venus Bulk Flow One

Common Name: Tooth shade resin material

Classification Name: Material, Tooth Shade, Resin

Regulation Number: 872.3690

Product Code(s): EBF

Bundling Rationale:

This 510(k) submission includes four polymer-based, tooth-shade resin materials regulated under 21 CFR 872.3690 (product code EBF). Because the devices share similar technology, intended use, testing methodologies, and risk profiles, bundling them into a single submission is appropriate and consistent with FDA's "*Bundling Multiple Devices or Multiple Indications in a Single Submission"* policy.

Legally Marketed Predicate Devices

For the purpose of substantial equivalence, the following primary predicates apply:

- Venus Diamond -> Neun (K073554)
- Venus Diamond Flow -> Venus Diamond Flow (K091635)
- Venus Pearl -> Venus Pearl PLT A1 (K112501)
- Venus Bulk Flow ONE -> Venus Bulk Flow ONE (K220605)

Reference Devices

Used to support methods/benchmarks for aligner-related indications:

- AlignerFlow LC (K231817) – DYH, 21 CFR 872.3750
- GC Ortho Connect / GC Ortho Etching Gel (Aligner Connect) (K150128) – DYH, 21 CFR 872.3750

Device Description

All four devices are **light-curing, radiopaque, polymer-based dental composites** (nano/nanohybrid) supplied in syringes and PLT units for professional use. They are applied in thin layers and polymerized using dental curing lights (typ. 450–480 nm; ~600–1550 mW/cm^2). Packaging sizes and handling characteristics (viscosity/flow for the "Flow" and "Bulk Flow" variants; modeling characteristics for "Diamond" and "Pearl") align with their intended use in direct restorations and related clinical procedures, including aligner attachment fabrication and retainer fixation.

Representative compositions include inorganic fillers (e.g., barium alumino-borosilicate glass, silica, ytterbium fluoride), dimethacrylate resins (e.g., UDMA, TEGDMA, TCD-urethaneacrylate, E4BADMA), initiators (e.g., camphorquinone), stabilizers (e.g., BHT), and pigments/fluorescent agents. Radiopacity meets **ISO 4049** acceptance criteria and is within the enamel/dentin-relevant ranges reported for each product.

Indications for Use (Per Device)

Venus Diamond:

Direct restorations of all cavity classes • Direct composite veneers • Shape corrections of teeth (i.e. diastemas, congenital defects in teeth, etc.) • Splinting of teeth • Restoration of primary teeth • Core build-up • Repairs of porcelain, composite (in combination with an adequate repair-system) • Composite attachments for aligner treatment • Fixation of retainers

Venus Diamond Flow:

• Enlarged fissure sealing • Cavity lining – as the first layer for Class I and II cavities • Class I, II, III, IV and V direct restorations • Small repairs of direct and indirect restorations combined with a suitable bonding agent • Splinting of teeth • Composite attachments for aligner treatment • Fixation of retainers

Venus Pearl:

• Direct restorations of all cavity classes • Direct composite veneers • Shape corrections of teeth (i.e. diastemas, congenital defects in teeth, etc.) • Splinting of teeth • Restoration of primary teeth • Core build-up • Repairs of porcelain, composite (in combination with an adequate repair-system) • Composite attachments for aligner treatment • Fixation of retainers

Venus Bulk Flow One:

• Class I, II, III, IV and V direct restorations • First-layer lining for class I and II cavities • Repair of direct and indirect restorations in combination with a suitable adhesive • Splinting of teeth • Extended fissure sealing • Composite attachments for aligner treatment • Fixation of retainers

Indications for Use Comparison – comparison to predicates & justification

All core restorative indications are **the same** as those of the respective primary predicates within 21 CFR 872.3690 (EBF). The added aligner-related indications (composite attachments; retainer fixation) fall within the **same intended use** (restorative/composite materials for intraoral application by dental professionals) and do **not** alter the devices' general purpose or mechanism of action. Performance aspects relevant to these uses (e.g., bond strength, depth of cure, wear, radiopacity, handling) are addressed by bench testing using methods and acceptance criteria aligned with polymer-based restorative materials, and by reference device experience for aligner applications; no **new** questions of safety or effectiveness are raised.

Differences between the subject devices' indications and those of the predicates do not alter the intended therapeutic use and do not raise new questions of safety or effectiveness. The added aligner-related uses fall within the same general intended use of polymer-based restorative composite systems as described in 21 CFR 807.92(a)(5).

Technological Comparison

Venus Bulk Flow One

Venus Bulk Flow One is a flowable, light curing, radio-opaque nano-hybrid composite. Venus Bulk Flow One's primary packaging consists of a 2.0 g syringe with a plunger and closing cap, intended for use at room temperature and 30–70% relative humidity. A prefilled 0.2g PLT and dispensing tips are used for dispensing the product. The composite is applied in thin layers (maximum 4 mm) to the designated area. Each layer is then individually polymerized using a suitable dental light-curing unit (e.g., Kulzer Translux®) with the following operating parameters: wavelength peak of 450–480 nm and light output of 1550–600 mW/cm^2.

The predicate device Venus Bulk Flow One (K220605) is also a flowable, light curing, radio-opaque nano-hybrid composite with an identical composition to the applicant device. The primary packaging is also a 2.0 g syringe with a plunger and closing cap, intended for use at room temperature and 30–70% relative humidity, a prefilled 0.2g PLT and dispensing tips are used for dispensing the product. The composite is applied in the same way as the application device, in thin layers (max. 4mm) to the designated area that are polymerized individually using a suitable dental light-curing unit. Immediately after polymerization, both the applicant and predicate devices are indicated for rough finishing using diamond burs and final shaping and contouring using a fine-grained diamond stone, a multi-blade tungsten carbide bur, polishing strips, finishing diamonds, flexible discs, silicone polishers, and polishing brushes.

	Applicant Device	**Predicate Device**	**Reference Device**	**Reference Device**
Trade Name	Venus Bulk Flow ONE	Venus Bulk Flow ONE	Aligner Flow LC	GC Ortho Connect, GC Ortho Etching Gel (Aligner Connect)
510(k)	N/A	K220605	K231817	K150128
Regulation Name	Tooth Shade Resin Material	Tooth Shade Resin Material	Bracket Adhesive Resin And Tooth Conditioner	Bracket Adhesive Resin And Tooth Conditioner
Regulation Number	21 CFR 872.3690	21 CFR 872.3690	21 CFR 872.3750	21 CFR 872.3750
Regulatory Class	Class II	Class II	Class II	Class II
Product Code	EBF	EBF	DYH	DYH
Prescription/OTC	Prescription	Prescription	Prescription	Prescription
Manufacturer	Kulzer GmbH	Kulzer GmbH	VOCO GmbH	GC Orthodontics America Inc.
Physical Properties	All physical properties of the applicant device are identical to previous predicate device "Venus Bulk Flow ONE" as no composition changes have been made. Depth of cure: min. 4.0 ± 0.5 mm Flexural strength: min. 100 MPa Wear Resistance: 117 ± 17 µm Dimension stability: 3.5 ± 0.1 %-vol Fluorescence: 118%	Depth of cure: min. 4.0 ± 0.5 mm Flexural strength: min. 100 MPa Wear Resistance: 117 ± 17 µm Dimension stability: 3.5 ± 0.1 %-vol Fluorescence: 118% Compatibility to aligner materials: 0.19 mm size reduction after 1000 cycles Bond Strength: Pass Microleakage: Low level of microleakage	Depth of cure: 2.3 mm Flexural strength: 128 MPa Wear Resistance: 143 ± 8 µm Dimension stability: 3.2 ± 0.1 %-vol Fluorescence: 134% Compatibility to aligner materials: 0.18 mm size reduction after 1000 cycles Bond Strength: Pass Microleakage: Low level of microleakage	Depth of cure: 3.5 mm Flexural strength: 115 MPa Wear Resistance: 138 ± 20 µm Dimension stability:3.7 ± 0.1 %-vol Fluorescence: 112% Compatibility to aligner materials: 0.20 mm size reduction after 1000 cycles Bond Strength: Pass Microleakage: Low level of microleakage

	Applicant Device	Predicate Device	Reference Device	Reference Device
	Compatibility to aligner materials: 0.19 mm size reduction after 1000 cycles Bond Strength: Pass Microleakage: Low level of microleakage			
Application Characteristics	The following steps represent the standard clinical procedure for direct composite restorations using Venus Bulk Flow ONE. These are consistent with generally accepted practices in restorative dentistry. 1. Tooth Preparation 2. Isolation 3. Matrix and Wedge Placement 4. Adhesive Application 5. Hygienic Sleeve Usage 6. Composite Placement 7. Alternative Usage 8. Light Curing 9. Layering 10. Optional Topcoat 11. Finishing and Polishing 12. Remove Protective Sleeve 13. Dispose of Cannula and Reseal 14. Do Not Reuse Contaminated Syringes 15. Dispose of Used PLT Note: Detailed instructions and specifications are provided in the product's official IFU. In addition to the steps listed above, further guidance has been included regarding aligner therapy, as follows Application of attachments for clear aligner therapy 1. fill the composite into the attachment's recesses of the template. Prepare the enamel to be treated as described under I. Filling therapy. Place the template on the prepared row of teeth and cure the	The following steps represent the standard clinical procedure for direct composite restorations using Venus Bulk Flow ONE. These are consistent with generally accepted practices in restorative dentistry. 1. Tooth Preparation 2. Isolation 3. Matrix and Wedge Placement 4. Adhesive Application 5. Hygienic Sleeve Usage 6. Composite Placement 7. Alternative Usage 8. Light Curing 9. Layering 10. Optional Topcoat 11. Finishing and Polishing 12. Remove Protective Sleeve 13. Dispose of Cannula and Reseal 14. Do Not Reuse Contaminated Syringes 15. Dispose of Used PLT Note: Detailed instructions and specifications are provided in the product's official IFU. Always refer to the IFU for comprehensive guidance.	The composite is used in the adhesive technique with a dentine enamel bond. Any light-curing bonding material can be used. The extruded composite is applied into the aligner template, placed on the prepared teeth and each attachment is light cured through the transparent template for the fabrication of attachments. Following removal of the attachment template, finish the attachments in accordance with generally applicable standards if and as necessary. Once the aligner treatment is completed, the attachments can be removed using a grinding/finishing diamond burr. Subsequent polishing of the tooth surface is then recommended. Excess material can be made visible on the tooth surface with a UV lamp (360-395 nm) and removed accordingly.	For bonding GC Aligner Connect to enamel and/or dentin, use a light-cured bonding system (e.g. G-Premio BOND). Follow bonding agent manufacturer's instructions. Place dispensing tip as close as possible to the transfer tray, and slowly push the plunger to extrude material. Set transfer tray in the oral cavity. Light cure GC Aligner Connect on each attachment area with an LED light curing device. Remove transfer tray from the oral cavity. If necessary, finish and polish using standard techniques. When orthodontic treatment no longer requires the attachment, remove attachment with diamond bur or silicon point.

	Applicant Device	Predicate Device	Reference Device	Reference Device
	attachments according to the table. 2. After completion of the clear aligner therapy, remove the composite attachments with rotating instruments and polish the tooth surface, e.g. Venus Supra. 3. UV-A -light may be used for detection in order to differentiate between composite and tooth substance.			

Venus Diamond Flow

Venus Diamond Flow is a flowable, light curing, radio-opaque nano-hybrid composite. Venus Diamond Flow's primary packaging is a 1.8g syringe with a plunger and a closing cap, intended for use at room temperature and 30–70% relative humidity. A prefilled 0.2g PLT and flow cannulas are used for dispensing the product. The composite is applied in thin layers (max. 2mm, baseliner max. 1mm) to the designated area. Each layer is then individually polymerized using a suitable dental light-curing unit (e.g., Kulzer Translux®) with the following operating parameters: wavelength peak of 450–480 nm and light output of 1550–600 mW/cm^2.

The predicate device Venus Diamond Flow (K091635) is a flowable, light curing, radio-opaque nano-hybrid composite with an identical composition to the applicant device. The primary packaging is also a 2.0g syringe with a plunger and a closing cap, intended for use at room temperature and 30–70% relative humidity, and a prefilled 1.8g PLT and flow cannulas are used for dispensing the product. The composite is applied in the same way as the application device, in thin layers (max. 2mm, baseliner max. 1mm) to the designated area that are polymerized individually using a suitable dental light-curing unit. Immediately after polymerization, both the applicant and predicate devices are indicated to be prepared and polished by finishing diamonds, flexible discs, silicone polishers and polishing brushes.

	Applicant Device	Predicate Device	Reference Device	Reference Device
Trade Name	Venus Diamond Flow	Venus Diamond Flow	Aligner Flow LC	GC Ortho Connect, GC Ortho Etching Gel (Aligner Connect)
510(k)	N/A	K091635	K231817	K150128
Regulation Name	Tooth Shade Resin Material	Sealant Pit and Fissure and Conditioner	Bracket Adhesive Resin and Tooth Conditioner	Bracket Adhesive Resin and Tooth Conditioner
Regulation Number	21 CFR 872.3690	21 CFR 872.3690	21 CFR 872.3750	21 CFR 872.3750
Regulatory Class	Class II	Class II	Class II	Class II
Product Code	EBF	EBF	DYH	DYH
Prescription/OTC	Prescription	Prescription	Prescription	Prescription

	Applicant Device	Predicate Device	Reference Device	Reference Device
Manufacturer	Kulzer GmbH	Kulzer GmbH	VOCO GmbH	GC Orthodontics America Inc.
Physical Properties	All physical properties of the applicant device are identical to previous predicate device “Venus Diamond Flow” as no composition changes have been made. Depth of cure: min. 2.0 ± 0.5 mm Flexural strength: min. 100 MPa Wear Resistance: 117 ± 17 µm Dimension stability: 3.5 ± 0.1 %-vol Fluorescence: 118% Compatibility to aligner materials: 0.15 mm size reduction after 1000 cycles Bond Strength: Pass Microleakage: Low level of microleakage	Depth of cure: min. 2.0 ± 0.5 mm Flexural strength: min. 100 MPa Wear Resistance: 117 ± 17 µm Dimension stability: 3.5 ± 0.1 %-vol Fluorescence: 118% Compatibility to aligner materials: 0.15 mm size reduction after 1000 cycles Bond Strength: Pass Microleakage: Low level of microleakage	Depth of cure: 2.3 mm Flexural strength: 128 MPa Wear Resistance: 143 ± 8 µm Dimension stability: 3.2 ± 0.1 %-vol Fluorescence: 134% Compatibility to aligner materials: 0.18 mm size reduction after 1000 cycles Bond Strength: Pass Microleakage: Low level of microleakage	Depth of cure: 3.5 mm Flexural strength: 115 MPa Wear Resistance: 138 ± 20 µm Dimension stability:3.7 ± 0.1 %-vol Fluorescence: 112% Compatibility to aligner materials: 0.20 mm size reduction after 1000 cycles Bond Strength: Pass Microleakage: Low level of microleakage
Application Characteristics	The following steps represent the standard clinical procedure for direct composite restorations using Venus Diamond Flow These are consistent with generally accepted practices in restorative dentistry. 1. Rubber Dam Placement 2. Cavity Preparation 3. Adhesive Application 4. Composite Placement 5. Light Curing 6. Layer 7. Finishing and Polishing Note: Detailed instructions and specifications are provided in the product’s official IFU. In addition to the steps listed above, further guidance has been included regarding aligner therapy, as follows Application of attachments for clear aligner therapy 1. fill the composite into the attachment's recesses of the template. Prepare the enamel to be treated as described under I. Filling therapy. Place the template on the prepared row of teeth and cure the	The following steps represent the standard clinical procedure for direct composite restorations using Venus Diamond Flow. These are consistent with generally accepted practices in restorative dentistry. 1. Rubber Dam Placement 2. Cavity Preparation 3. Adhesive Application 4. Composite Placement 5. Light Curing 6. Layer 7. Finishing and Polishing Note: Detailed instructions and specifications are provided in the product’s official IFU. Always refer to the IFU for comprehensive guidance.	The composite is used in the adhesive technique with a dentine enamel bond. Any light-curing bonding material can be used. The extruded composite is applied into the aligner template, placed on the prepared teeth and each attachment is light cured through the transparent template for the fabrication of attachments. Following removal of the attachment template, finish the attachments in accordance with generally applicable standards if and as necessary. Once the aligner treatment is completed, the attachments can be removed using a grinding/finishing diamond burr. Subsequent polishing of the tooth surface is then recommended. Excess material can be made visible on the tooth surface with a UV lamp (360-395 nm) and removed accordingly.	For bonding GC Aligner Connect to enamel and/or dentin, use a light-cured bonding system (e.g. G-Premio BOND). Follow bonding agent manufacturer’s instructions. Place dispensing tip as close as possible to the transfer tray, and slowly push the plunger to extrude material. Set transfer tray in the oral cavity. Light cure GC Aligner Connect on each attachment area with an LED light curing device. Remove transfer tray from the oral cavity. If necessary, finish and polish using standard techniques. When orthodontic treatment no longer requires the attachment, remove attachment with diamond bur or silicon point.

	Applicant Device	Predicate Device	Reference Device	Reference Device
	attachments according to the table. 2. After completion of the clear aligner therapy, remove the composite attachments with rotating instruments and polish the tooth surface, e.g. Venus Supra. 3. UV-A -light may be used for detection in order to differentiate between composite and tooth substance.			

Venus Diamond

Venus Diamond is a light-curing, radiopaque nano-composite. Its primary packaging consists of a 4.0 g syringe with a plunger and closing cap. The product should be used above room temperature, within 30–70% relative humidity, and may be heated for use up to a maximum of 129 °F. The individual application quantity of the composite for the treatment is usually taken from the syringe and presented in a tray using a sterile dental instrument. Otherwise a prefilled 0.25g PLT is used for dispensing the product. The composite is applied in thin layers (max. 1mm-2mm, depending on shade) to the designated area. Each layer is then individually polymerized using a suitable dental light-curing unit (e.g., Kulzer Translux®) with the following operating parameters: wavelength peak of 450–480 nm and light output of 1550–600 mW/cm^2.

The predicate device Neun (K073554) is also a light curing, radio-opaque nano composite with an identical composition to the applicant device. The primary packaging is also a 4.0g syringe with a plunger and a closing cap and a prefilled 0.25g PLT. The composite is applied in the same way as the application device, in thin layers (max. 1mm-2mm, depending on shade) to the designated area that are polymerized individually using a suitable dental light-curing unit. After final build up and polymerization is completed, both the applicant and predicate devices are indicated to be finished and polished by diamond burs, fine-grained diamond stones, multi-fluted carbide burs, silicone rubber polishing points, cups, discs, or similar tools.

	Applicant Device	Predicate Device	Reference Device	Reference Device
Trade Name	Venus Diamond	Neun	Aligner Flow LC	GC Ortho Connect, GC Ortho Etching Gel (Aligner Connect)
510(k)	N/A	K073554	K231817	K150128
Regulation Name	Tooth Shade Resin Material	Tooth Shade Resin Material	Bracket Adhesive Resin And Tooth Conditioner	Bracket Adhesive Resin And Tooth Conditioner
Regulation Number	21 CFR 872.3690	21 CFR 872.3690	21 CFR 872.3750	21 CFR 872.3750
Regulatory Class	Class II	Class II	Class II	Class II
Product Code	EBF	EBF	DYH	DYH
Prescription/OTC	Prescription	Prescription	Prescription	Prescription
Manufacturer	Kulzer GmbH	Kulzer GmbH	VOCO GmbH	GC Orthodontics America Inc.
Physical Properties	All physical properties of the applicant device are identical to previous predicate device “Neun” as no composition changes have been made. Depth of cure: min. 2.0 ± 0.5 mm Flexural strength: min. 130 MPa Wear Resistance: 153 ± 9 µm Dimension stability: 1.7 ± 0.1 %-vol Fluorescence: 118% Compatibility to aligner materials: 0.15 mm size reduction after 1000 cycles Bond Strength: Pass	Depth of cure: min. 2.0 ± 0.5 mm Flexural strength: min. 130 MPa Wear Resistance: 153 ± 9 µm Dimension stability: 1.7 ± 0.1 %-vol Fluorescence: 118% Compatibility to aligner materials: 0.15 mm size reduction after 1000 cycles Bond Strength: Pass Microleakage: Low level of microleakage	Depth of cure: 2.3 mm Flexural strength: 128 MPa Wear Resistance: 143 ± 8 µm Dimension stability: 3.2 ± 0.1 %-vol Fluorescence: 134% Compatibility to aligner materials: 0.18 mm size reduction after 1000 cycles Bond Strength: Pass Microleakage: Low level of microleakage	Depth of cure: 3.5 mm Flexural strength: 115 MPa Wear Resistance: 138 ± 20 µm Dimension stability:3.7 ± 0.1 %-vol Fluorescence: 112% Compatibility to aligner materials: 0.20 mm size reduction after 1000 cycles Bond Strength: Pass Microleakage: Low level of microleakage

	Applicant Device	Predicate Device	Reference Device	Reference Device
	Microleakage: Low level of microleakage			
Application Characteristics	The following steps represent the standard clinical procedure for direct composite restorations using Venus Diamond. These are consistent with generally accepted practices in restorative dentistry. 8. Rubber Dam Placement 9. Cavity Preparation 10. Adhesive Application 11. Composite Placement 12. Light Curing 13. Layer 14. Finishing and Polishing Note: Detailed instructions and specifications are provided in the product's official IFU. In addition to the steps listed above, further guidance has been included regarding aligner therapy, as follows Application of attachments for clear aligner therapy 1. Fill the composite into the attachment's recesses of the template. Prepare the enamel to be treated as described under I. Filling therapy. Place the template on the prepared row of teeth and cure the attachments according to the table. 2. After completion of the clear aligner therapy, remove the composite attachments with rotating instruments and polish the tooth surface, e.g. Venus Supra. 3. UV-A -light may be used for detection in order to differentiate between composite and tooth substance.	The following steps represent the standard clinical procedure for direct composite restorations using Venus Diamond. These are consistent with generally accepted practices in restorative dentistry. 1. Rubber Dam Placement 2. Cavity Preparation 3. Adhesive Application 4. Composite Placement 5. Light Curing 6. Layer 7. Finishing and Polishing Note: Detailed instructions and specifications are provided in the product's official IFU. Always refer to the IFU for comprehensive guidance.	The composite is used in the adhesive technique with a dentine enamel bond. Any light-curing bonding material can be used. The extruded composite is applied into the aligner template, placed on the prepared teeth and each attachment is light cured through the transparent template for the fabrication of attachments. Following removal of the attachment template, finish the attachments in accordance with generally applicable standards if and as necessary. Once the aligner treatment is completed, the attachments can be removed using a grinding/finishing diamond burr. Subsequent polishing of the tooth surface is then recommended. Excess material can be made visible on the tooth surface with a UV lamp (360-395 nm) and removed accordingly.	For bonding GC Aligner Connect to enamel and/or dentin, use a light-cured bonding system (e.g. G-Premio BOND). Follow bonding agent manufacturer's instructions. Place dispensing tip as close as possible to the transfer tray, and slowly push the plunger to extrude material. Set transfer tray in the oral cavity. Light cure GC Aligner Connect on each attachment area with an LED light curing device. Remove transfer tray from the oral cavity. If necessary, finish and polish using standard techniques. When orthodontic treatment no longer requires the attachment, remove attachment with diamond bur or silicon point.

The tables differ mainly in **indications for use**, **physical properties**, and **application steps**, with applicant devices adding **aligner-related functions** not found in predicates, while reference devices are **aligner-only**. Regulation numbers, trade names, and 510(k) listings also vary across devices.

Venus Pearl

Venus Pearl is a light curing, radio-opaque nanocomposite. Its primary packaging is a 3.0g syringe with a plunger and a closing cap. The product should be used above room temperature, within 30–70% relative humidity, and may be heated for use up to a maximum of 129 °F. The individual application quantity of the composite for the treatment is usually taken from the syringe and presented in a tray using a sterile dental instrument. Otherwise a prefilled 0.2g PLT is used for dispensing the product. The composite is applied in thin layers (max. 1mm-3mm, depending on shade) to the designated area. Each layer is then individually polymerized using a suitable dental light-curing unit (e.g., Kulzer Translux®) with the following operating parameters: wavelength peak of 450–480 nm and light output of 1550–600 mW/cm^2.

The predicate device Venus Pearl PLT Refill A1 (K112501) is also a light curing, radio-opaque nano composite with an identical composition to the applicant device. The primary packaging is also a 3.0g syringe with a plunger and a closing cap and a prefilled 0.2g PLT. The composite is applied in the same way as the application device, in thin layers (max. 1mm-3mm, depending on shade) to the designated area that are polymerized individually using a suitable dental light-curing unit. After final build up and polymerization is completed, both the applicant and predicate devices are indicated for gross finishing using diamond burs and final shaping and finishing using fine-grained diamond stones, multifluted carbide burs, abrasive strips, flexible silicone rubber polishing points, cups, discs, or similar tools.

	Applicant Device	Predicate Device	Reference Device	Reference Device
Trade Name	Venus Pearl	VENUS PEARL PLT REFILL A1	Aligner Flow LC	GC Ortho Connect, GC Ortho Etching Gel (Aligner Connect)
510(k)	N/A	K112501	K231817	K150128
Regulation Name	Tooth Shade Resin Material	Tooth Shade Resin Material	Bracket Adhesive Resin And Tooth Conditioner	Bracket Adhesive Resin And Tooth Conditioner
Regulation Number	21 CFR 872.3690	21 CFR 872.3690	21 CFR 872.3750	21 CFR 872.3750
Regulatory Class	Class II	Class II	Class II	Class II
Product Code	EBF	EBF	DYH	DYH
Prescription/OTC	Prescription	Prescription	Prescription	Prescription
Manufacturer	Kulzer GmbH	Kulzer GmbH	VOCO GmbH	GC Orthodontics America Inc.
Physical Properties	All physical properties of the applicant device are identical to previous predicate device “Venus Pearl” as no composition changes have been made. Depth of cure: min. 2.0 ± 0.5 mm Flexural strength: min. 125 MPa Wear Resistance: 131 ± 6 µm Dimension stability: 1.9 ± 0.1 %-vol	Depth of cure: min. 2.0 ± 0.5 mm Flexural strength: min. 125 MPa Wear Resistance: 131 ± 6 µm Dimension stability: 1.9 ± 0.1 %-vol Fluorescence: 116% Compatibility to aligner materials: 0.14 mm size reduction after 1000 cycles Bond Strength: Pass	Depth of cure: 2.3 mm Flexural strength: 128 MPa Wear Resistance: 143 ± 8 µm Dimension stability: 3.2 ± 0.1 %-vol Fluorescence: 134% Compatibility to aligner materials: 0.18 mm size reduction after 1000 cycles Bond Strength: Pass	Depth of cure: 3.5 mm Flexural strength: 115 MPa Wear Resistance: 138 ± 20 µm Dimension stability:3.7 ± 0.1 %-vol Fluorescence: 112% Compatibility to aligner materials: 0.20 mm size reduction after 1000 cycles Bond Strength: Pass

	Applicant Device	Predicate Device	Reference Device	Reference Device
	Fluorescence: 116% Compatibility to aligner materials: 0.14 mm size reduction after 1000 cycles Bond Strength: Pass Microleakage: Low level of microleakage	Microleakage: Low level of microleakage	Microleakage: Low level of microleakage	Microleakage: Low level of microleakage
Application Characteristics	The following steps represent the standard clinical procedure for direct composite restorations using Venus Pearl. These are consistent with generally accepted practices in restorative dentistry. 1. Rubber Dam Placement 2. Cavity Preparation 3. Adhesive Application 4. Composite Placement 5. Light Curing 6. Layer 7. Finishing and Polishing Note: Detailed instructions and specifications are provided in the product's official IFU. In addition to the steps listed above, further guidance has been included regarding aligner therapy, as follows Application of attachments for clear aligner therapy 1. Fill the composite into the attachment's recesses of the template. Prepare the enamel to be treated as described under I. Filling therapy. Place the template on the prepared row of teeth and cure the attachments according to the table. 2. After completion of the clear aligner therapy, remove the composite attachments with rotating instruments and polish the tooth surface, e.g. Venus Supra. 3. UV-A -light may be used for detection in order to differentiate between	The following steps represent the standard clinical procedure for direct composite restorations using Venus Pearl. These are consistent with generally accepted practices in restorative dentistry. 1. Rubber Dam Placement 2. Cavity Preparation 3. Adhesive Application 4. Composite Placement 5. Light Curing 6. Layer 7. Finishing and Polishing Note: Detailed instructions and specifications are provided in the product's official IFU. Always refer to the IFU for comprehensive guidance.	The composite is used in the adhesive technique with a dentine enamel bond. Any light-curing bonding material can be used. The extruded composite is applied into the aligner template, placed on the prepared teeth and each attachment is light cured through the transparent template for the fabrication of attachments. Following removal of the attachment template, finish the attachments in accordance with generally applicable standards if and as necessary. Once the aligner treatment is completed, the attachments can be removed using a grinding/finishing diamond burr. Subsequent polishing of the tooth surface is then recommended. Excess material can be made visible on the tooth surface with a UV lamp (360-395 nm) and removed accordingly.	For bonding GC Aligner Connect to enamel and/or dentin, use a light-cured bonding system (e.g. G-Premio BOND). Follow bonding agent manufacturer's instructions. Place dispensing tip as close as possible to the transfer tray, and slowly push the plunger to extrude material. Set transfer tray in the oral cavity. Light cure GC Aligner Connect on each attachment area with an LED light curing device. Remove transfer tray from the oral cavity. If necessary, finish and polish using standard techniques. When orthodontic treatment no longer requires the attachment, remove attachment with diamond bur or silicon point.

	Applicant Device	Predicate Device	Reference Device	Reference Device
	composite and tooth substance.			

Each table above includes a different applicant and corresponding predicate device; however, each applicant device aligns appropriately with its designated predicate. Each applicant device also demonstrates different material performance values based on its specific requirements. While the application instructions share a similar overall structure and content, the individual steps and level of detail differ. Despite these variations, none introduce new questions of safety or effectiveness relative to the primary predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Testing was performed on representative shades/viscosities of the four devices using recognized consensus standards and validated internal methods, as applicable. All tests met prespecified acceptance criteria and/or applicable standard requirements.

Performance Testing Summary (as required under 807.92(b)(1)):

Flexural Strength (ISO 4049): All devices exceeded ≥100 MPa requirement; comparable to predicates.
– **Radiopacity (ISO 4049):** All devices met ≥1 mm/100% Al threshold; results 2.0–3.5 mm Al.
– **Depth of Cure:** Achieved claimed depths (e.g., 4 mm for Bulk Flow).
– **Wear Resistance:** Comparable to predicates under simulated masticatory cycling.
– **Bond Strength:** Acceptable enamel/dentin adhesion comparable to reference aligner materials.
– **Thermal Cycling:** No degradation affecting performance.
– **Biocompatibility:** Cytotoxicity, sensitization, irritation, and systemic assessments passed.
All tests support substantial equivalence.
The following FDA-recognized consensus standards were applied, as required under 21 CFR 807.92(b)(1):
– ISO 4049: Dentistry — Polymer-based restorative materials
– ISO 10993-5 / -10 / -11: Biological evaluation of medical devices
Internal validated methods for depth of cure, wear, shrinkage, surface polishability, thermal testing, and handling properties were used.
All testing met or exceeded acceptance criteria.

Both the applicant and the predicate/reference devices use the same testing methods which conclude through biocompatibility, bench, and thermal testing that the applicant devices perform as well or better than the selected predicate/reference devices.

Clinical Data Statement (807.92(b)(2)):

No clinical data was submitted, referenced, or relied upon to support this submission. Non-clinical performance data was sufficient to establish substantial equivalence.

Substantial Equivalence Conclusion:

The non-clinical data demonstrate that Venus Diamond, Venus Diamond Flow, Venus Pearl, and Venus Bulk Flow ONE are as safe, as effective, and perform as well as their respective primary predicates for the stated indications. Differences in indications limited to aligner attachments and retainer fixation do not change the intended use or raise new questions of safety or effectiveness; performance expectations are addressed by bench testing and informed by reference device experience for these specific applications. The devices therefore meet the requirements for substantial equivalence under 21 CFR 807.92(b)(3).