March 14, 2025

Kettenbach GmbH & Co. KG
Marleen Steger
Regulatory Affairs Manager
Im Heerfeld 7
Eschenburg, 35713
Germany

Re: K250267
Trade/Device Name: Visalys® Bulk Fill 1 x 4 g Syringe (15060); Visalys® Bulk Fill 15 x 0.25 g Caps (15062); Visalys® Bulk Flow 1 x 2 g Syringe (15064); Visalys® Bulk Flow 15 x 0.25 g Caps (15066); Visalys® Bulk Flow Intro pack (15067); Visalys® Bulk Intro pack (15068)
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: March 13, 2025
Received: March 13, 2025

Dear Marleen Steger:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250267

Device Name
Visalys® Bulk Fill 1 x 4 g Syringe (15060); Visalys® Bulk Fill 15 x 0.25 g Caps (15062); Visalys® Bulk Flow 1 x 2 g Syringe (15064); Visalys® Bulk Flow 15 x 0.25 g Caps (15066); Visalys® Bulk Flow Intro pack (15067); Visalys® Bulk Intro pack (15068)

Indications for Use *(Describe)*
Visalys® Bulk Fill: Loss of tooth substance due to caries, fractures, dental wear or developmental disorders. Techniques: Class I and II restorations, non-tunneled class III restorations, class V restorations, filling in deciduous teeth, core build-ups, cavity floor elevation, repair of direct and indirect restorations after appropriate pretreatment and splinting / locking of teeth.

Visalys® Bulk Flow: Loss of tooth substance due to caries, fractures, dental wear or developmental disorders. Techniques: Class I and II restorations, non-tunneled class III restorations, class V restorations, filling in deciduous teeth, core build-ups, cavity lining, cavity floor elevation, blocking out undercuts, repair of direct and indirect restorations after appropriate pretreatment, extended fissure sealing and splinting / locking of teeth.

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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K250267 - 510(k) Summary

I. Submitter:

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Date of preparation: March 14th, 2025

II. Device

Name of Device:	Visalys® Bulk Fill
Common or Usual Name:	Visalys® Bulk Fill
Classification Name:	Material, Tooth Shade, Resin (21 CFR 872.3690)
Regulatory Class:	II
Product Code:	EBF

Name of Device:	Visalys® Bulk Flow
Common or Usual Name:	Visalys® Bulk Flow
Classification Name:	Material, Tooth Shade, Resin (21 CFR 872.3690)
Regulatory Class:	II
Product Code:	EBF

III. Predicate devices:

Venus Bulk Flow ONE (Kulzer, LLC), K220605
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. Device Description:

Visalys® Bulk Fill is a light-cured, nano-hybrid filling composite that can be modeled and is available in a universal shade. For adhesive cementation, a dentin-enamel bond is used. The material is available in screw syringes and caps and can be applied in layers up to 4 mm thick. The filling material contains approx. 82% inorganic fillers by weight. The radiopacity is 2.5 mm aluminium*. The color stability meets the requirements of DIN EN ISO 4049. Visalys® Bulk Fill is thus suitable for both posterior teeth and also for fillings without tunnel preparation in the anterior tooth area, particularly class III and V.

Visalys® Bulk Flow is a light-cured, flowable nano-hybrid filling composite and is available in a universal shade. For adhesive cementation, a dentin-enamel bond is used. The material is available in syringes and caps and can be applied in layers up to 4 mm thick. The filling material contains approx. 72% inorganic fillers by weight. The radiopacity is 2.0 mm aluminium*. The color stability meets the requirements of DIN EN ISO 4049. Visalys® Bulk Flow is thus suitable for both posterior teeth and also for fillings without tunnel preparation in the anterior tooth area, particularly class III and V. Capping is not necessary.

*Aluminium has the same radiopacity as dentin. 1 mm enamel corresponds to 2 mm aluminium.

V. Indications for Use:

Visalys® Bulk Fill

Loss of tooth substance due to caries, fractures, dental wear or developmental disorders.

Techniques:

- Class I and II restorations
- Non-tunneled class III restorations
- Class V restorations
- Fillings in deciduous teeth
- Core build-ups
- Cavity floor elevation
- Repair of direct and indirect restorations after appropriate pretreatment
- Splinting / locking of teeth

Visalys® Bulk Flow

Loss of tooth substance due to caries, fractures, dental wear or developmental disorders.

Techniques:

- Class I and II restorations
- Non-tunneled class III restorations
- Class V restorations
- Fillings in deciduous teeth
- Core build-ups
- Cavity lining
- Cavity floor elevation
- Blocking out undercuts
- Repair of direct and indirect restorations after appropriate pretreatment
- Extended fissure sealing
- Splinting / locking of teeth

VI. Table 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Predicate Devices	Substantial Equivalent Device		Conclusion
Product	Venus Bulk Flow ONE	Visalys® Bulk Fill	Visalys® Bulk Flow	
Manufacturer	Kulzer, LLC	Kettenbach GmbH & Co. KG		
Product Description	Venus Bulk Flow ONE is a flowable, light-curing, radio-opaque nano-hybrid composite.	Visalys® Bulk Fill is a light-cured, nano-hybrid filling composite that can be modeled and is available in a universal shade.	Visalys® Bulk Flow is a light-cured, flowable nano-hybrid filling composite and is available in a universal shade.	Visalys® Bulk Fill and Visalys® Bulk Flow are similar to Venus Bulk Flow One. All are light-cured nano-hybrid composites.
Intended purpose	Flowable light curing nano hybrid composite, radio-opaque	Universal nano-hybrid restorative composite, modelable	Universal nano-hybrid restorative composite, flowable	Visalys® Bulk Fill and Visalys® Bulk Flow are similar to Venus Bulk Flow One. These are light-cured, nano-hybrid composites. Visalys® Bulk Fill is modelable, Visalys® Bulk Flow and Venus Bulk Flow ONE are flowable. The differences in viscosity have no effect on the intended purpose. Visalys® Bulk Fill and Visalys® Bulk Flow are radio-opaque like Venus Bulk Flow ONE, which is not described in the intended purpose.
Indications / Techniques	- Class -I, -II, -III 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 loosened teeth resulting from trauma or periodontal associated events	- Class I and II restorations - Non-tunneled class III restorations - Class V restorations - Fillings in deciduous teeth - Core build-ups - Cavity floor elevation - Repair of direct and indirect restorations after appropriate pretreatment	- Class I and II restorations - Non-tunneled class III restorations - Class V restorations - Fillings in deciduous teeth - Core build-ups - Cavity lining - Cavity floor elevation - Blocking out undercuts	All Venus Bulk Flow ONE indications are covered by Visalys® Bulk Fill and Visalys® Bulk Flow. Visalys® Bulk Fill and Visalys® Bulk Flow can also be used for fillings in deciduous teeth, core build-ups, cavity floor elevation and blocking out undercuts (just Visalys® Bulk Flow).

	Predicate Devices	Substantial Equivalent Device		Conclusion
Product	Venus Bulk Flow ONE	Visalys® Bulk Fill	Visalys® Bulk Flow	
Manufacturer	Kulzer, LLC	Kettenbach GmbH & Co. KG		
	- Extended fissure sealing	- Splinting / locking of teeth	- Repair of direct and indirect restorations after appropriate pretreatment - Extended fissure sealing - Splinting / locking of teeth	
Basic formulation	Venus Bulk Flow ONE is a light-curing methacrylate-based formulation with the following ingredients: Barium aluminium boro-fluoro-silicate glass, E4BADMA, UDMA, ytterbium fluoride, silicium dioxide, titanium dioxide, BHT, aminobenzoic acid ester, camphorquinone, fluorescent pigments, metal oxide pigments, organic pigments. Venus Bulk Flow ONE contains approx. 41 % filler by vol., the particle size of which is 20 nm – 5 µm.	Main components of Visalys® Bulk Fill are approx. 61 vol. % inorganic fillers in the size range 0.01 – 5 µm including ytterbium fluoride. The polymer base consists of aliphatic dimethacrylates.	Main components of Visalys® Bulk Flow are approx. 47 vol. % inorganic fillers in the size range 0.01 – 5 µm including ytterbium fluoride. The polymer base consists of aliphatic dimethacrylates.	The basic formulation is similar. The products are methacrylate based and contain inorganic fillers including ytterbium fluoride. The particle sizes are the same.
Available shades	Universal shade	Universal shade	Universal shade	The products are available in a one-shade system for all tooth shades.
Single use	Single use only	Single use only	Single use only	The products are single use devices.
Application system	Syringe (2 g)	Syringe (4 g) Cap (0.25 g)	Syringe (2 g) Cap (0.25 g)	All products are available in a syringe. Visalys® Bulk Fill and Visalys® Bulk Flow are also offered in a cap.
Performance testing	A comparison of the parameters in respect to mechanical properties was performed. The results demonstrate the substantial equivalence to the predicate device.			
Summary of Product	The indication of the subject devices is the same for the predicate device. Contraindications, application, and side effects for both products are basically the same – there is a slight difference in the wording.			

	Predicate Devices	Substantial Equivalent Device		Conclusion
Product	Venus Bulk Flow ONE	Visalys® Bulk Fill	Visalys® Bulk Flow	
Manufacturer	Kulzer, LLC	Kettenbach GmbH & Co. KG		
Description, Intended purpose Indications, Contraindications / Precautions				
Summary Chemical Composition	The Visalys® Bulk Flow formulation has been thoroughly assessed for biocompatibility. The results for Visalys® Bulk Flow covers Visalys® Bulk Fill since the most relevant ingredients from a toxicological standpoint are present in a higher concentration in Visalys® Bulk Flow.			
Summary of Finished Device Specification	The results demonstrate the substantial equivalence to the predicate device.			

VII. Performance Data:

Biocompatibility:

The following performance data were provided in support of the substantial equivalence determination. The biocompatibility evaluation was conducted in accordance with ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.:

- Cytotoxicity ISO 10993-5
- Sensitization ISO 10993-10
- Genotoxicity ISO 10993-3
- Toxicological risk assessment ISO 10993-17
- Chemical characterization ISO 10993-18
- Evaluation of biocompatibility ISO 7405

The tests showed that the biocompatibility data of Visalys® Bulk Flow (and therefore Visalys® Bulk Fill) is comparable to other materials on the market. Hence, no toxicological risks and resulting hazards for patients, users and third parties can be concluded.

Non-clinical performance:

According to ISO 4049 "Polymer-based restorative materials" bench testing was performed to allow an evaluation of the mechanical properties of Visalys® Bulk Fill and Visalys® Bulk Flow in comparison to Venus Bulk Flow ONE (K220605).

Sensitivity to light	Acc. to ISO 4049 / 7.9
Depth of cure	Acc. to ISO 4049 / 7.10
Flexural strength	Acc. to ISO 4049 / 7.11
Elastic modulus	Acc. to ISO 4049 / 7.11
Water sorption	Acc. to ISO 4049 / 7.12
Solubility	Acc. to ISO 4049 / 7.12
Shade of restorative materials	Acc. to ISO 4049 / 7.13 and ISO 7491 / ANSI ADA Spec. 80
Color stability after irradiation and water sorption	Acc. to ISO 4049 / 7.13 and ISO 7491 / ANSI ADA Spec. 80
Radio-opacity	Acc. to ISO 4049 / 7.14 and ISO 13116
Volume shrinkage	Acc. to ISO 17304
Shear bond strength to dentin	Acc. to ISO 29022
Shear bond strength to restorative materials	Acc. to ISO 29022
Duration of light curing	Internal test method
Extrusion force[1)]	Internal test method
Consistency[2)]	Internal test method
High shear viscosity[1)]	Internal test method
Low shear viscosity[1)]	Internal test methods
Universal color	In-vitro test

[1)] Test just for Visalys® Bulk Flow; [2)] Test just for Visalys® Bulk Fill

Summary:
Based on the performance data, Visalys® Bulk Fill and Visalys® Bulk Flow were found to have a safety and effectiveness profile that is similar to the predicate device.

Clinical Performance Data:
Data from clinical studies was not provided.

VIII. Conclusion:

Based on similarities in technology and indications for use, together with results on non-clinical performance testing, Visalys® Bulk Fill and Visalys® Bulk Flow are substantially equivalent to the predicate device Venus Bulk Flow ONE (K220605).