



November 8, 2019

Kettenbach GmbH & Co. KG
Katja Simon
Regulatory Affairs Manager
Im Heerfeld 7
Eschenburg, 35713 De

Re: K191527

Trade/Device Name: Visalys CemCore, Visalys Cem Core Try In Paste
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: August 9, 2019
Received: August 12, 2019

Dear Katja Simon:

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,

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K191527

Device Name
Visalys® CemCore
Visalys® CemCore Try In Paste

Indications for Use (Describe)

Visalys® CemCore is a dual-curing, adhesive cementation and core build-up composite, which is intended to be used for:

- a) Permanent cementation of
- crowns, bridges, inlays, onlays, veneers and adhesive bridges made of metal, ceramic, composite, hybrid and oxide ceramics
 - root posts and indirect core build-ups
- b) Composite for
- adhesive core build-ups

Visalys® CemCore Try In Paste is a water-soluble polyethylene glycol paste for shade matching:

- To check the shade selected prior to permanent cementation with Visalys® CemCore.
- For covering the cement joint to reduce a layer of inhibition.

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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K191527

510(k) Summary

A. Name and address of manufacturer:

Kettenbach GmbH & Co KG
Im Heerfeld 7
35713 Eschenburg
Germany
Establishment Registration No.: 9681356
Owner/Operator Number: 9022134

Name, title and phone number of official correspondent:

Simon, Katja
Regulatory Affairs Manager
Im Heerfeld 7
35713 Eschenburg
Germany
Phone: + 49 277 4705 0
E-mail: katja.simon@kettenbach.com

Name, title and phone number of U.S. Agent (Contact):

Roggenbau, Wilfried
InterGest North America LLC.
400 Oser Ave., Suite 1650
Hauppauge, NY 11788
Phone: 631 5010500 ext
Fax: 631 5011060
Email: roggenbauw@intergestna.com

Date of preparation: October 30th, 2019



B. Device Identification: **Visalys® CemCore**
 Device Trade Name: Visalys® CemCore
 Versions: Universal (A2/A3), Dark (A4), Opaque, Bleach, Translucent
 Common Name: Dual-curing, adhesive cementation and core build-up composite

Device Identification: **Visalys® CemCore Try In Paste**
 Device Trade Name: Visalys® CemCore Try In Paste
 Versions: Universal (A2/A3), Dark (A4), Opaque, Bleach, Translucent
 Common Name: Water-soluble polyethylene glycol paste for shade matching

Classification of the device (Visalys® CemCore/Visalys® CemCore Try In Paste):
 Device Classification Name: Dental cement
 1. Product Code: EMA
 2. Product Code: EBF
 Device Classification No.: Part 872.3690
 Panel: Dental
 Regulatory Status: Class II

C. Predicate devices:

Applicant Product	Product Type	Product Code	Predicate Device	510(k) No.	Product Code	Applicant
Visalys CemCore	Dental Cement	EBF	Visalys Core (Secondary Predicate)	K143104	EBF	Kettenbach GmbH & Co. KG
			Multilink Automix (Primary Predicate)	K123397	EBF	Ivoclar Vivadent
Visalys Try In Paste	Try In Paste	EBF	RelyX™ Try-In Paste	K002452	EMA	3M Espe



D. Device Description:

Visalys® CemCore is a dual-curing composite containing fluoride for adhesive cementation of indirect restorations and root posts and can be used to fabricate radiopaque core build-ups and abutment fillings. Due to the Active-Connect-Technology (ACT) Visalys® CemCore includes an additional initiator system for the optimization of the adhesive bond. BPA or BPA precursors are not used in the manufacturing process of this device.

Visalys® CemCore shall only be used in combination with self-etching Visalys® Tooth Primer. Visalys® Restorative Primer is recommended as the primer for the restoration surfaces. Visalys® CemCore is easy to use and has high adhesive strength and good flowability with stable consistency.

Visalys® CemCore is offered in the shades Universal (A2/A3), Dark (A4), Opaque, Bleach and Translucent.

The paste should be mixed and dispensed directly from a double syringe with the corresponding mixing tips blue (MLø 3.2 mm).

Visalys® CemCore Try in Paste serves to simulate the shade effect of the selected Visalys® CemCore shade on ceramic restorations and for covering the cement joint to reduce a layer of inhibition. The water-soluble paste corresponds in shade and translucence with the completely cured Visalys® CemCore.

Visalys® CemCore Try In Paste is offered in the shades Universal (A2/A3), Dark (A4), Opaque, Bleach and Translucent.

The paste is dispensed from a syringe and syringe tip.



E. Indications for Use:

Visalys® CemCore is a dual-curing, adhesive cementation and core build-up composite, which is intended to be used for:

- a) Permanent cementation of
 - crowns, bridges, inlays, onlays, veneers and adhesive bridges made of metal, ceramic, composite, hybrid and oxide ceramics
 - root posts and indirect core build-ups

- b) Composite for
 - adhesive core build-ups

Visalys® CemCore Try In Paste water-soluble polyethylene glycol paste for shade matching

- To check the shade selected prior to permanent cementation with Visalys® CemCore.
- For covering the cement joint to reduce a layer of inhibition.

F. Table 1: Comparison of technological characteristic with the predicate devices

	Predicate Devices		Substantial Equivalent Device	Conclusion
Product	Visalys [®] Core (Secondary Predicate)	Multilink [®] Automix (Primary predicate)	Visalys [®] CemCore	
Manufacturer	Kettenbach	Ivoclar Vivadent	Kettenbach GmbH & Co. KG	
Cure type	Dual cure	Dual cure	Dual cure	
Product Description	Visalys Core is a dual-curing, fluoride-containing composite used for the fabrication of radiopaque core build-ups and core fillings.	Multilink [®] Automix is a self-curing luting composite with light-curing option for the adhesive luting of indirect restorations made of metal, metal-ceramic, all-ceramic and composite.	Visalys [®] CemCore is a dual-curing adhesive containing fluoride for adhesive cementation of indirect restorations and root posts. Moreover, Visalys [®] CemCore can be used to fabricate radiopaque core build-ups and abutment fillings.	Visalys [®] CemCore is similar to Multilink [®] Automix (Primary Predicate). Additionally, Visalys [®] CemCore could also be used for adhesive core build-ups.
Indication	<ul style="list-style-type: none"> - Different types of core build-ups - Luting of root posts 	<p>Multilink Automix and Multilink Primer are used for the permanent cementation of indirect restorations where a strong bond is desired:</p> <ul style="list-style-type: none"> – Inlays, onlays, crowns, bridges and root posts made of – metal and metal-ceramics – all-ceramics, in particular opaque zirconium oxide ceramics – composites and fibre-reinforced composites 	<p>Permanent cementation of:</p> <ul style="list-style-type: none"> - crowns, bridges, inlays, onlays, veneers and adhesive bridges made of metal, ceramic, composite, hybrid and oxide ceramics. - root posts and indirect core build-ups <p>Composite for:</p> <ul style="list-style-type: none"> - adhesive core build-ups 	<p>Visalys[®] CemCore is similar to Multilink[®] Automix (Primary Predicate). Visalys[®] CemCore could also be used for adhesive core build-ups as well as Visalys Core(Secondary Predicate)</p>



	Predicate Devices		Substantial Equivalent Device	Conclusion
Product	Visalys [®] Core (Secondary Predicate)	Multilink [®] Automix (Primary predicate)	Visalys [®] CemCore	
Manufacturer	Kettenbach	Ivoclar Vivadent	Kettenbach GmbH & Co. KG	
Cure type	Dual cure	Dual cure	Dual cure	
Storage temperature	4-24 °C / 40-75 °F	2-28°C	2-8 °C/36-46 °F	A storage in a fridge is for Visalys [®] CemCore recommended
Available Shades	Dentin, White, Blue	Shades Multilink Automix is available in four shades with different degrees of translucency: – transparent (high translucency) – yellow (high translucency) – opaque (low translucency) – white (medium translucency)	Shades: Universal (A2/A3), Dark (A4), Opaque, Bleach und Translucent.	Similar to Multilink [®] Automix (Primary Predicate), Visalys [®] CemCore uses the same color range, an additional color Dark (A4) was included
Application system	1:1 cartridge 1:1 syringe	1:1 syringe	1:1 syringe	Identical to Multilink [®] Automix (Primary Predicate) and Visalys [®] Core (Secondary Predicate). All uses the identical syringe system
A comparison of parameters in respect to processing time/mechanical properties was performed. The results demonstrated the substantial equivalence to the predicate devices.				



G. Table 2: Device comparison Visalys® CemCore Try In Paste

	Predicate Devices	Substantial Equivalent Device	Conclusion
Product	RelyX™ Try-In Paste	Visalys® Try In Paste	
Manufacturer	3M Espe	Kettenbach GmbH & Co. KG	
Product Description	RelyX™ Try-In Pastes are used to guide the dentist in the selection of the shade required for the final cementation with 3M™ ESPE™ RelyX™ Veneer cement and RelyX Ultimate adhesive resin cement. The shades of RelyX Try-In paste specifically match the final cured shade of RelyX Veneer cement and RelyX Ultimate cement.	Visalys® CemCore Try In Paste serves to simulate the shade effect of the selected Visalys® CemCore shade on ceramic restorations. The water-soluble paste corresponds in shade and translucence with the completely cured Visalys® CemCore. Visalys® CemCore Try In Paste is offered in the shades Universal (A2/A3), Dark (A4), Opaque, Bleach and Translucent. Note: Only once the cementation composite Visalys® CemCore is fully polymerized and has attained its final shade, the shade coordination with the try-in paste is attained. Visalys® CemCore Try In Paste only corresponds with the shades of Visalys® CemCore.	Similar, Visalys® CemCore Try in Paste and the predicate have the same indication.
Indications	Paste for shade matching	<ul style="list-style-type: none"> - Paste for shade matching - For covering the cement joint to reduce a layer of inhibition 	The indication of both devices is identical. Visalys® Try In Paste can also be used for covering the cement joint to reduce a layer of inhibition
Storage temperature	2 – 25 °C/36 – 77 °F.	15 – 25 °C/59 –77 °F.	For Visalys® CemCore Try in Paste storage at room Temperature is recommended.
Application system	Syringe	Syringe	Similar
The results demonstrated the substantial equivalence to the predicate devices.			



H. Substantial Equivalence:

Visalys[®] CemCore / Visalys[®] CemCore Try In Paste have the same indication as the above listed predicate devices (Table 1 and 2).

The technological characteristics of Visalys[®] CemCore / Visalys[®] CemCore Try In Paste are also substantially equivalent (Table 1 and 2).

I. Non-Clinical Performance Testing:

Visalys[®] CemCore

Biocompatibility tests have been performed to assure biological safety in accordance with the ISO 10993 family and ISO 7405. Tests in respect to cytotoxicity (ISO 10993-5), mutagenicity (OECD 487), sensitization (ISO 10993-10) and a chemical analysis (10993-18) showed, that the biocompatibility data of Visalys[®] CemCore is comparable to other materials on the market. Therefore no toxicological risks and resulting hazards for patients, users and third parties can be concluded.

Additionally bench testing was performed to allow an evaluation of the mechanical properties of Visalys[®] CemCore in comparison to Visalys[®] Core (K143104/Secondary Predicate) and Multilink[®] Automix (K123397/Primary Predicate).

Working time	acc. to ISO 4049 / 7.6_7.7 and ASTM D 4473
Cure point	acc. to ISO 4049 / 7.8 and ASTM D 4473
Depth of cure	acc. to ISO 4049 / 7.10
Film thickness	acc. to ISO 4049 / 7.5
Volume shrinkage	acc. to ISO 4049 /17304
Water sorption	acc. to ISO 4049 / 7.12
Solubility	acc. to ISO 4049 / 7.12
Radio-opacity	acc. to ISO 4049 / 7.14
E-Modulus (self-cure)	acc. to ISO 4049 / 7.11
Flexural strength (self-cure)	acc. to ISO 4049 / 7.11
Compressive strength (self-cure)	acc. to ISO 9917-1, Annex D
Diametral tensile strength (light-cure)	acc. to ADA Specification No. 27 section 4.3.7
Shade consistency	Reproduction of color shades/ANSI ADA Spec. 80
Color stability	acc. to ISO 4049, section 7.13 and ISO 7491/ANSI ADA Spec. 80 acc. to ISO 7491, section 3.2.3
Visual comparison Visalys CemCore / Visalys CemCore Try In Paste	Color comparison according to ISO 7491, section 3.2.3, with three persons who perceive color normally



Rheological properties	internal test method
Shear bond strength	ISO 20922/16506 ISO 16506 (Chapter A 2.2.5).

Visalys[®] CemCore Try In Paste

Biocompatibility tests have been performed to assure biological safety in accordance with the ISO 10993 family and ISO 7405. Tests in respect to cytotoxicity (ISO 10993-5) and a chemical analysis (10993-18) showed, that the biocompatibility data of Visalys[®] CemCore Try In Paste is comparable to other materials on the market. Therefore no toxicological risks and resulting hazards for patients, users and third parties can be concluded.

Additionally bench testing was performed to allow an evaluation of the properties of Visalys[®] CemCore Try In Paste

Visual comparison Visalys [®] CemCore / Visalys [®] CemCore Try In Paste	Color comparison according to ISO 7491, section 3.2.3, with three persons who perceive color normally.
Layer of inhibition	Internal test: Comparison between the surfaces with and without Visalys [®] CemCore Try In Paste, with three persons which haptically evaluated the stickiness of the different surfaces after curing with or without the previous application of the Visalys [®] CemCore Try In Paste

J. Clinical Performance Data

Visalys[®] CemCore / Visalys[®] CemCore Try In Paste

Data from clinical studies was not provided.



K. Conclusion:

Based on similarities in technology and on indications for use, together with results non-clinical performance testing, we believe that Visalys[®] CemCore and Visalys[®] CemCore Try In Paste are substantially equivalent to the predicate devices.