October 9, 2019

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

Re: K191523
Trade/Device Name: Visalys Restorative Primer
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: September 4, 2019
Received: September 9, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191523

Device Name
Visalys® Restorative Primer

Indications for Use *(Describe)*

Restoration primer for treatment of:
metal/silicate ceramics, oxide ceramic and composite surfaces
• to cement prosthetic restorations
• to repair fractured restorations with composite materials

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.

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510(k) Summary

In accordance with the requirements of the Safe Medical Device Act, Kettenbach GmbH & Co KG herewith submits a 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:

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

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Fax: 631 5011060
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Date of preparation: September 04th, 2019

B. Device Identification: Visalys® Restorative Primer

Device Trade Name:	Visalys® Restorative Primer
Common Name:	Universal adhesion primer for restoration materials

Classification of the device:

Device Classification Name:	Resin tooth bonding agent
Product Code:	KLE
Device Classification No.:	Part 872.3200
Panel:	Dental
Regulatory Status:	Class II

C. Predicate device:

Device Trade Name:	CLEARFIL™ CERAMIC PRIMER PLUS
Applicant:	Kuraray Noritake Dental Inc.
510(k) No.:	K150703

D. Device Description:

Visalys® Restorative Primer with adhesive monomers (10-MDP, silane methacrylate) is for building up adhesive surfaces on restoration materials (metal, composite, as well as silicate and oxide ceramics). Visalys® Restorative Primer is a single component primer. Do not light cure Visalys® Restorative Primer. BPA or BPA precursors are not used in the manufacturing process of this device.

E. Indications for use:

Restoration primer for treatment of:
metal/silicate ceramics, oxide ceramic and composite surfaces
- to cement prosthetic restorations
- to repair fractured restorations with composite materials

F. Comparison of technological characteristic with the predicate devices

	Predicate Devices	Substantial Equivalent Device	Conclusion
Product	CLEARFIL™ CERAMIC PRIMER PLUS	Visalys® Restorative Primer	
Manufacturer	Kuraray Noritake Dental Inc.	Kettenbach GmbH & Co. KG	
510(k) numbers	K150703	K191523	
Product Description	CLEARFIL™ CERAMIC PRIMER PLUS is a dental universal prosthetic primer that provides an enhanced adhesive surface to ceramic (e.g. conventional porcelain, lithium disilicate, zirconia), hybrid ceramics (e.g. ESTENIA C&B), composite resin and metal.	Visalys® Restorative Primer with adhesive monomers (10-MDP, silane methacrylate) is for building up adhesive surfaces on restoration materials (metal, composite, as well as silicate and oxide ceramics). Visalys® Restorative Primer is a single component primer that does not have to be light-cured.	Similar
Indication for use	Indications: CLEARFIL™ CERAMIC PRIMER PLUS is indicated for the following uses: [1] Surface treatment of prosthetic restorations made of ceramic, hybrid ceramics, composite resin or metal [2] Intraoral repairs of fractured restorations made of ceramics, hybrid ceramics, composite resin or metal	Indications: Restoration primer for treatment of metal/silicate ceramics, oxide ceramic and composite surfaces • to cement prosthetic restorations • to repair fractured restorations with composite materials	Similar
Storage temperature	2 – 8 °C/36 – 46 °F	2 – 8 °C/35 – 46 °F	Similar
Application system	Bottle	Bottle	Similar
Composition	• 3-Methacryloxypropyl trimethoxysilane • 10-Methacryloyloxydecyl dihydrogen phosphate (MDP) • Ethanol	The main components of the Visalys® Restorative Primer are ethanol, acidic adhesive monomer (10-MDP) and silane methacrylate.	Similar

	Predicate Devices	Substantial Equivalent Device	Conclusion
Product	CLEARFIL™ CERAMIC PRIMER PLUS	Visalys® Restorative Primer	
Manufacturer	Kuraray Noritake Dental Inc.	Kettenbach GmbH & Co. KG	
510(k) numbers	K150703	K191523	
Shear bond strengths on different restorative materials (ISO 16506 / Chapter A 2.2.5):			
Lithium disilicate	(8.9 MPa)	(10.2 MPa)	Similar
Zirconium oxide	(8.4 MPa)	(7.5 MPa)	Similar
Non-precious metal	(8.3 MPa)	(12.5 MPa)	Similar
Products used in the testing	CLEARFIL™ Ceramic Primer Plus (K150703) was tested with the resin product Panavia V5 dental cement (K150704), manufactured by Kuraray	Visalys® Restorative Primer (K191523) was tested with the resin product Visalys CemCore (K191527), manufactured by Kettenbach GmbH & Co. KG.	
Product description and composition for the predicate device has been extracted from the instruction for use. Values given in brackets have been determined by Kettenbach			

Table 1: Visalys® Restorative Primer product description and characteristic to predicate device

G. Technological Characteristics Summary:

Visalys® Restorative Primer is considered substantially equivalent to Clearfil Ceramic Primer Plus. There is no significant difference in intended use or technology. Therefore Visalys® Restorative Primer is substantially equivalent to the above listed predicate device. Differences in respect to chemical composition and resulting mechanical and physical properties have been evaluated.

H. Summary of Non-Clinical Performance Testing:

The following in vitro bench tests were performed on the Visalys® Restorative Primer to verify physical properties and performance in support of substantial equivalence:

- Shear Bond strength on restorative materials acc. to ISO 16506 “Dentistry – Polymer-based luting materials containing adhesive component shear bond strength test” (Chapter A 2.2.5).

The performance of the Visalys® Restorative Primer satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence.

Biocompatibility tests have been performed to assure biological safety in accordance with the ISO 10993 family and ISO 7405. Tests in respect of cytotoxicity (ISO 10993-5), mutagenicity (OECD 487), sensitization (ISO 10993-10) and a chemical analysis (10993-18) showed, that Visalys® Restorative Primer, universal adhesion primer for restoration materials biocompatibility data is comparable or superior to the predicate device. Therefore no toxicological risks and resulting hazards for patients, users and third parties can be concluded.

Rationale for using ISO 16506 (Chapter A 2.2.5) as test standard

The Medical Device Product Classification for the stated product is KLE (Agent, Tooth Bonding, Resin). However, the stated product Visalys® Restorative Primer acts as a coupling agent between restoration material (e.g. ceramics, metals) and luting material (e.g. Visalys® CemCore) and not between luting material and tooth structure. For the later indication, Visalys® Tooth Primer can be used.
The recognized test standards ISO 29022 and ISO/TS 11405 as well as ISO/TS 16506 describe different bonding strength measurements. Unfortunately, all three standards only show methods to determine bond strength to tooth structure. As no product-specific standard exists for the subject device, testing was conducted under ISO/TS 16506 due to the following reason:
Shear bond strength is described in ISO 29022 and in ISO/TS 16506. The main difference is the loading of the test specimen after application of the luting material in ISO/TS 16506 (force of 150 N ± 2N, Ch 7.5.1.2), whereas no force is applied in the test method described in ISO 29022. Visalys® Restorative Primer is used on restorations such as crowns, bridges, inlays and onlays. After applying a luting material on the restoration, it is placed in the patient’s mouth onto a tooth,

core or into a cavity by applying a force onto the restoration to maintain a small layer thickness of the luting material. Therefore, the shear bond test method described in ISO/TS 16506 is a more realistic measurement for this kind of product (Visalys® Restorative Primer) due to the loading of the test specimen, which simulates the above-mentioned clinical procedure.
ISO/TS 11405 gives a general overview of techniques for examination of adhesion. Once again, only procedures for testing of the adhesion to tooth structure are included (title of the standard: “Testing of adhesion to tooth structure”). Annex A describes methods for the measurement of bond strength. As explained above, shear bond strength of Visalys® Restorative Primer was already tested according to ISO/TS 16506. An additional bond strength measurement is e.g. micro-tensile bond strength, as described in Annex A, A.2.4. Unfortunately, such measurement cannot be performed with restorative materials because there is no practicable way to cut restorative materials (e.g. metals like titanium) into the desired dimension of 1 mm x 1 mm. Additionally, no force can be applied on the luting material to simulate the clinical procedure (see above). For a detailed description of micro-tensile bond strength and the challenging test procedure to prepare test specimen, see S. Armstrong et al. (1)

1. Armstrong, S. *et al*. Academy of Dental Materials guidance on in vitro testing of dental composite bonding effectiveness to dentin / enamel using micro-tensile bond strength (μTBS) approach. Dent. Mater. 33, 133–143 (2016).

I. Clinical Performance Data

No data from human clinical studies has been included to support the substantial equivalence of Visalys® Restorative Primer.

J. Conclusion Regarding Substantial Equivalence:

Kettenbach GmbH & Co KG believes that Visalys® Restorative Primer, universal adhesion primer for restoration materials is substantially equivalent to Clearfil Ceramic Primer Plus (K150703). It does not introduce new indications for use, has similar technological characteristics and does not introduce new potential hazards or safety risks.