September 29, 2019

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

Re: K191524
Trade/Device Name: Visalys Tooth Primer
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: August 27, 2019
Received: August 30, 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,

Srinivas Nandkumar
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)*
K191524

Device Name
Visalys® Tooth Primer

Indications for Use *(Describe)*

For permanent cementation of tooth structure to:
• crowns, bridges, inlays, onlays, veneers and adhesive bridges in combination with Visalys® CemCore

• root posts in combination with Visalys® CemCore and Visalys® Core

• indirect core build-ups in combination with Visalys® CemCore

For build-up adhesive bond to structure with Visalys® CemCore and Visalys® Core to fabricate:

• adhesive core build-ups

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:

Simon, Katja
Regulatory Affairs Manager
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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.
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Hauppauge, NY 11788
Phone: 631 5010500 ext
Fax: 631 5011060
Email: roggenbauw@intergestna.com

Date of preparation: August 26th, 2019

B. Device Identification: Visalys® Tooth Primer

Device Trade Name:	Visalys® Tooth Primer
Common Name:	self-etching single component primer for the tooth hard substance

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:	Panavia™ V5 Tooth Primer
Applicant:	Kuraray Noritake Dental Niigata Plant
510(k) No.:	K150704

D. Device Description:

Visalys® Tooth Primer is a self-etching single-component primer with acidic polymers (10-MDP) for adhesive bonding of Visalys® CemCore and Visalys® Core to the dental hard substance. The primer can be applied without additional etching or after selective etching the enamel. Do not light cure Visalys® Tooth Primer. BPA or BPA precursors are not used in the manufacturing process of this device.

E. Indications for use:

For permanent cementation of tooth structure to:

- crowns, bridges, inlays, onlays, veneers and adhesive bridges in combination with Visalys® CemCore
- root posts in combination with Visalys® CemCore and Visalys® Core
- indirect core build-ups in combination with Visalys® CemCore

For build-up adhesive bond to structure with Visalys® CemCore and Visalys® Core to fabricate:

- adhesive core build-up

F. Comparison of technological characteristic with the predicate devices

	Predicate Devices	Substantial Equivalent Device	Conclusion
Product	Panavia V5 TOOTH PRIMER	Visalys® Tooth Primer	
Manufacturer	Kuraray	Kettenbach GmbH & Co. KG	
510(k)	K150704	K191524	
Product Description	The Tooth Primer is a self-etching primer to tooth structure that accelerates the polymerization of the Paste	Visalys® Tooth Primer is a self-etching single-component primer with acidic polymers (10-MDP) for adhesive bonding of Visalys®CemCore and Visalys® Core to the dental hard substance. The primer can be applied without additional etching or after selective etching the enamel. Visalys® Tooth Primer does not have to be cured with light.	Similar
Indications for use	PANAVIA V5 is indicated for the following uses: [1] Cementation of crowns, bridges, inlays and onlays [2] Cementation of veneers [3] Cementation of adhesion bridges and splints [4] Cementation of prosthetic restorations on implant abutments and frames [5] Cementation of posts and cores [6] Amalgam bonding	For permanent cementation of tooth structure to: • crowns, bridges, inlays, onlays, veneers and adhesive bridges in combination with Visalys® CemCore • root posts in combination with Visalys® CemCore and Visalys® Core • indirect core build-ups in combination with Visalys® CemCore For build-up adhesive bond to structure with Visalys® CemCore and Visalys® Core to fabricate: • adhesive core build-ups	Similar
Storage temperature	2-8°C/36-46°F	/2-8°C/36-46°F	Similar
Application system	Bottle	Bottle	Similar
A comparison of parameters in respect to processing time/mechanical properties was performed. The results demonstrated the substantial equivalence to the predicate device.			

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

G. Technological Characteristics Summary:

Visalys® Tooth Primer is considered substantially equivalent to Panavia V5 Tooth Primer. There is no significant difference in intended use or technology. Therefore Visalys® Tooth 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® Tooth Primer to verify physical properties and performance in support of substantial equivalence:

- Shear Bond strength on enamel and dentin according to ISO 29022 “Denistry – Adhesion – Notched edge shear bond strength test”

The performance of the Visalys® Tooth 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® Tooth Primer, self-etching single component primer for the tooth hard substance’s 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.

I. Clinical Performance Data

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

J. Conclusion Regarding Substantial Equivalence:

Kettenbach GmbH & Co KG believes that Visalys® Tooth Primer, self-etching single component primer for the tooth hard substance is substantially equivalent to Panavia V5 tooth primer (K150704). It does not introduce new indications for use, has similar technological characteristics and does not introduce new potential hazards or safety risks.

The fact that the indication for use for Visalys® Tooth Primer does not include bonding to amalgam does not interfere with the substantial equivalency to the predicate device, Panavia V5 tooth primer (K150704) since by international convention, usage of mercury-containing dental amalgam is to be reduced. Likewise, it was not tested (Press Release U.S. Department of State, PRN: 2013/1353, https://2009-2017.state.gov/r/pa/prs/ps/2013/11/217295.htm)