June 11, 2021

Kuraray Noritake Dental Inc.
Yasujiro Ohara
Manager
Ote Center Bldg. 7F, 1-1-3, Otemachi
Chiyoda-ku, Tokyo 100-0004
JAPAN

Re: K210504/S001
Trade/Device Name: PANAVIA Veneer LC
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: April 13, 2021
Received: April 16, 2021

Dear Yasujiro Ohara:

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,

Michael E. Adjodha, M.ChE.
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)*
K210504

Device Name
PANAVIA Veneer LC

Indications for Use *(Describe)*
[1] Cementation of ceramic and composite inlays, onlays and laminate veneers with less than 2mm thickness

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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Date: 10th June, 2021

510(k) Summary: K210504

5-1. 510(k) owner (submitter)

1) Name	Kuraray Noritake Dental Inc.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person	Yasujiro Ohara Manager Quality Assurance Department
4) Contact person in US	Manabu Suzuki Director Dental Material Division KURARAY AMERICA, INC. 33 Maiden Lane, 6th Floor, New York, NY 10038 Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676 Fax: (212)-867-3543

5-2. Name of Device

1) Trade / Proprietary name	PANAVIA Veneer LC
2) Classification name	Dental cement (21 CFR section section: 872.3275. Product code: EMA)
3) Common name	Dental adhesive resin cement

5-3. Predicate devices

1) PANAVIA V5 (Primary predicate device)	510(k) Number: Classification: Product Code: 21 CFR Section: Applicant:	K150704 Dental cement EMA 872.3275 Kuraray Noritake Dental Inc.
2) CLEARFIL MAJESTY ES Flow (Predicate device)	510(k) Number Classification: Product Code: 21 CFR Section: Applicant:	K191980 Tooth shade resin material EBF 872.3690 Kuraray Noritake Dental Inc.
3) CLEARFIL Universal Bond Quick (Reference device)	510(k) Number: Classification: Product Code: 21 CFR Section: Applicant:	K161042 Resin tooth bonding agent KLE 872.3200 Kuraray Noritake Dental Inc.
4) KATANA AVENCIA Block (Reference device)	510(k) Number: Classification: Product Code: 21 CFR Section: Applicant:	K153476 Tooth shade resin material EBF 872.3690 Kuraray Noritake Dental Inc.

The relationship between the subject device and each device are shown as follows.

PANAVIA V5 (Primary predicate device)	According to ISO 4049: 2009, this predicate device is classified as dual-cure (light-curing and self-curing) luting material (Type 2 - Class 3 - Group 1). The subject device is classified as light-curing luting material (Type 2 - Class 2 - Group 1). Therefore, The predicate device has the same performance for light-curing luting material as the subject device. Intended use and technological characteristics are almost same as the subject device.
CLEARFIL MAJESTY ES Flow (Predicate device)	According to ISO 4049: 2009, this predicate device is classified as a Type 2 - Class 2 - Group 1 luting material when using for cementation as same as the subject device. Intended use and technological characteristics for cementation are almost same as the subject device.
CLEARFIL Universal Bond Quick (Reference device)	Those devices are chosen to explain the Equivalence of Safety for Chemical Ingredient. And those are the same category (the external communicating device (tissue/ bone/ dentin) and permanent contact device) as the subject device.
KATANA AVENCIA Block (Reference device)	

5-4. Device Description

PANAVIA Veneer LC is a light-cure adhesive resin cement system. It consists of the light-cure cement paste (PANAVIA Veneer LC paste), CLEARFIL CERAMIC PRIMER PLUS, K-ETCHANT Syringe, and PANAVIA V5 Try-in Paste. CLEARFIL Universal Bond Quick or PANAVIA V5 Tooth Primer can be chosen for tooth treatment.

The cement paste is a light-cure, resin based material which provides color stability and has radiopacity equal to or greater than 1mm aluminum. It is indicated for inlays, onlays and laminate veneer restorations made of ceramic and composite resin. It is supplied in Kuraray's ergonomic syringe and dispensed via an

angled applicator tip (16G) into an inlay cavity or onto an onlay or a laminate veneer. It is available in 4 shades; Universal (A2), Clear, Brown (A4) and White. It is classified as a Type 2 and Class 2 (Group 1) material by ISO 4049. Shade adaptation is available to check by PANAVIA V5 Try-in Paste before cementation. This is the new registration application for the subject device and there have not been any prior submissions regarding the subject device.

We are seeking clearance for PANAVIA Veneer LC paste in this submission.

Concerning Try-in Paste which is included as components of the PANAVIA V5, CLEARFIL Universal Bond Quick, CLEARFIL CERAMIC PRIMER PLUS and K-ETCHANT Syringe, the specification of those 4 components were omitted for the reasons set forth below.
We already have had 510(k) clearance of Try-in Paste of PANAVIA V5(510(k) Number: 150704), CLEARFIL Universal Bond Quick (510(k) Number: 161042), CLEARFIL CERAMIC PRIMER PLUS (510(k) Number: 150703) and K-ETCHANT Syringe (510(k) Number: 133078).

5-5. Statement of Intended Use

The subject device is indicated for the following uses:

[1] Cementation of ceramic and composite inlays, onlays and laminate veneers with less than 2mm thickness

5-6. Substantial Equivalence Discussion

1) Intended uses

The intended use of the subject device and the predicate devices are listed on the following table.

	Trade name	Intended use
Subject device	PANAVIA Veneer LC	[1] Cementation of ceramic and composite inlays, onlays and laminate veneers with less than 2mm thickness
Predicate devices	PANAVIA V5 (Primary predicate device)	[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
	CLEARFIL MAJESTY ES Flow (Predicate device)	[1] Direct restorations for all cavity classes, cervical lesions (e.g. root surface caries, v-shape defects), tooth wear, and tooth erosion [2] Cavity base / liner [3] Correction of tooth position and tooth shape (e.g. diastema closure, tooth malformation) [4] Intraoral repair of fractured restorations [5] Cementation of ceramic and composite inlays, onlays and veneers with less than 2mm thickness

The intended use of the subject device was written up based on the Intended use [1] and [2] of primary predicate device and the Intended use [5] of Predicate device.

Therefore, the intended use of the subject device is substantially equivalent to those of the predicate devices.

2) Chemical ingredients/ Safety

Except for new ingredients, all ingredients have been used in the predicate devices as described in “Section 12: Substantial Equivalence Discussion”. Regarding these predicate devices and reference devices, there have not been any reported problems or recalls according to the post market adverse event reporting requirements in the US.

We evaluated the subject device referring to “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff”, ISO 10993 series and ISO 7405. As a result of the tests, it was concluded that the subject device is substantially equivalent in biological safety to the predicate devices and reference devices.

3) Comparison of Technological characteristics/ Effectiveness and Performance

Physical and mechanical properties of the subject device were evaluated according to ISO 4049: 2009 (Dentistry - Polymer-based restorative and materials).

The results of comparative study performed according to ISO 4049: 2009 were indicated below.

Section	Requirement	PANAVIA Veneer LC (Subject device)		PANAVIA V5 (Primary predicate device)	CLEARFIL MAJESTY ES Flow (Predicate device)
		Shade type 1: Clear Class 2	Shade type 2: White Class 2	Shade type: Universal (A2) Class 3	Class 2
5.2.2 Film thickness, luting materials	<50μm.	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.7 Sensitivity to ambient light	The material shall remain physically homogeneous.	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.8 Depth of cure	Shade type 1 and Predicate device: Not less than 1.5mm. Shade type 2: Not less than 1.0mm.	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.9 Flexural strength	Equal to or greater than 50 MPa.	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.10 Water sorption and solubility	≦40 μg/mm^3.	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
	≦7.5 μg/mm^3.	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.4 Color stability after irradiation and water sorption	No more than a slight change in color shall be observed for luting materials.	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.5 Radio-opacity	Equal to or greater than that of the same thickness of aluminium and no less than 0.5 mm of any value claimed by the manufacturer.	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***

The results indicate that the subject device and the predicate devices comply with the requirements of ISO 4049: 2009. From the above, it can be said that comparative study of the subject device is substantially equivalent to that of the predicate devices.

The result of Bond strength test

Adherend surface (Material composition)	Criteria	Subject device	Primary predicate device	
Tooth dentin	In-house standard	***COMPLIES***	***COMPLIES***	PANAVIA V5
Tooth enamel		***COMPLIES***	***COMPLIES***	
Ceramic		***COMPLIES***	***COMPLIES***	
Composite resin		***COMPLIES***	***COMPLIES***	
Hybrid ceramic		***COMPLIES***	***COMPLIES***	

The bond strengths to all substrates of the subject device were not statistically (P>0.05) different from that of the primary predicate device.
Therefore, it was concluded that the bonding performance to all substrates of the subject device was equivalent to that of the predicate device.

Released fluorine ion test was performed to validate the substantial equivalence of the subject device with the primary predicate device.
It was concluded that amount of released fluorine ion from the subject device is substantially equivalent to that of the predicate device.

5-7. Biocompatibility

The subject device is categorized into the external communicating device (tissue/ bone/dentin) and permanent contact device. There are new ingredients in the subject device.
Therefore, we evaluated the subject device referring to “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff”, ISO 10993 series and ISO 7405. The above results led us to the conclusion that the subject device was substantially equivalent in safety to the predicate devices and reference devices.

On the other hand, except for new ingredients on the subject device, all ingredients in the subject device have been used in the predicate device and the reference devices as described in “Section 12: Substantial Equivalence Discussion”.
Regarding these the predicate device and the reference devices, there have not been any reported problems or recalls according to the post market adverse event reporting requirements in the US.

Accordingly, it was considered that the subject device was substantially equivalent in safety to the predicate devices and reference devices.

5-8. Conclusion

The comparison for intended uses, chemical ingredients/ safety and performance data shows that the subject device is substantially equivalent to the predicate devices and reference devices.
This submission information including the nonclinical testing provided supports that the subject device is as safe and as effective as the predicate devices.