December 13, 2023

Kuraray Noritake Dental Inc.
Yasujiro Ohara
General Manager
Tokiwabashi Tower, 2-6-4, Otemachi
Chiyoda-ku, Tokyo 100-0004
JAPAN

Re: K231039
Trade/Device Name: CLEARFIL Universal Bond Quick 2
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: November 13, 2023
Received: November 13, 2023

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 (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.

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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, 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)*

Device Name
CLEARFIL Universal Bond Quick 2

Indications for Use *(Describe)*
[1] Direct restorations using light-cured composite resin
[2] Sealing of a prepared cavity or abutment tooth as a pretreatment for indirect restorations
[3] Treatment of exposed root surfaces
[4] Treatment of hypersensitive teeth
[5] Intraoral repairs of fractured restorations
[6] Post cementation and core build-ups
[7] Cementation of indirect restorations

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Date: 11th December, 2023

510(k) Summary

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 General Manager Quality Assurance Department
4) Contact person in US	Manabu Suzuki Director Dental Material Division KURARAY AMERICA, INC. 32 Old Slip, 7th Floor, New York, NY 10005 Tel: (212)-356-3940 (Ext. 115) or (800)-879-1676 Fax: (888)-700-5200

5-2. Name of Device

1) Trade / Proprietary name	CLEARFIL Universal Bond Quick 2
2) Classification name	Agent, Tooth Bonding, Resin (21 CFR section: 872.3200. Product code: KLE)
3) Common name	Dental Bonding agent

5-3. Predicate devices

1) CLEARFIL Universal Bond Quick (Primary predicate device)	510(k) Number	K161042
	Classification:	Agent, Tooth Bonding, Resin
	Product Code:	KLE
	21 CFR Section:	872.3200
	Applicant:	Kuraray Noritake Dental Inc.
2) BeautiBond Xtreme (Predicate device)	510(k) Number	K213965
	Classification:	Agent, Tooth bonding, Resin
	Product Code:	KLE
	21 CFR Section:	872.3200
	Applicant:	Shofu Dental Corporation
3) ESTENIA C&B (Reference device)	510(k) Number	K042929
	Classification:	Material, Tooth shade, Resin
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	Kuraray Noritake Dental Inc.

5-4. Device Description

CLEARFIL Universal Bond Quick 2 consists of BOND and K-ETCHANT Syringe. BOND is a light-cure bonding agent that allows for the treatment of dentin, enamel, and prosthetic materials. Depending on the indication, BOND is used as self-etching or with K-ETCHANT Syringe for selective enamel etching or total-etching procedures. BOND is intended to be used for both direct and indirect restorations. CLEARFIL DC Activator activates the dual-curing mechanism of BOND; however, the addition of CLEARFIL DC Activator to the adhesive is not required when using BOND with CLEARFIL DC CORE PLUS, self-adhesive resin cements manufactured by Kuraray Noritake Dental Inc. (Kuraray's self-adhesive cements, e.g. PANAVIA SA Cement Universal) or PANAVIA Veneer LC. K-ETCHANT Syringe is an etching gel that consists of 35 % phosphoric acid aqueous solution and colloidal silica.
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 CLEARFIL Universal Bond Quick 2 BOND in this permission.
Concerning K-ETCHANT Syringe which is included as components of CLEARFIL Universal Bond Quick 2, the specification of the component was omitted since we already have had 510(k) clearance of K-ETCHANT Syringe (510(k) Number: 133078).

5-5. Statement of Intended Use

The subject device is indicated for the following uses:
[1] Direct restorations using light-cured composite resin
[2] Sealing of a prepared cavity or abutment tooth as a pretreatment for indirect restorations
[3] Treatment of exposed root surfaces
[4] Treatment of hypersensitive teeth
[5] Intraoral repairs of fractured restorations
[6] Post cementation and core build-ups
[7] Cementation of indirect restorations

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	CLEARFIL Universal Bond Quick 2	[1] Direct restorations using light-cured composite resin [2] Sealing of a prepared cavity or abutment tooth as a pretreatment for indirect restorations [3] Treatment of exposed root surfaces [4] Treatment of hypersensitive teeth [5] Intraoral repairs of fractured restorations [6] Post cementation and core build-ups [7] Cementation of indirect restorations
Primary predicate device	CLEARFIL Universal Bond Quick	[1] Direct restorations using light-cured composite resin [2] Cavity sealing as a pretreatment for indirect restorations [3] Treatment of exposed root surfaces [4] Treatment of hypersensitive teeth [5] Intraoral repairs of fractured restorations [6] Post cementation and core build-ups [7] Cementation of indirect restorations
Predicate device	BeautiBond Xtreme	[1] Direct restorations with light-cured composite resin [2] Repair of fractured restorations with light-cured composite resin [3] Post cementation and core build-up [4] Cementation of indirect restorations with light-cured/dual-cured resin cement [5] Treatment of hypersensitive teeth or exposed root surface [6] Sealing of tooth preparation (cavity or abutment) for indirect restorations

The intended use of the subject device is substantially equivalent to that of CLEARFIL Universal Bond Quick (Primary predicate device) or BeautiBond Xtreme (Predicate device).

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

2) Chemical ingredients/ Safety

All ingredients have been used in the primary predicate device or the reference device as described in “Section 12: Substantial Equivalence Discussion”. Regarding these primary predicate device and reference device, 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 evaluation, it was concluded that the subject device is substantially equivalent in biological safety to the primary predicate device and the reference device.

3) Comparison of Technological characteristics/ Effectiveness and Performance

Since there have not been any international standards concerning performance of this type of device, certain tests were performed on this device, in comparison with the primary predicate device and it was confirmed that this device was substantially equivalent to the primary predicate device in terms of the effectiveness and performance.
Shear/tensile bond strength and Fluoride release testing were performed to validate the substantial equivalence of the subject device with the primary predicate device in terms of safety and effectiveness. The test has met all the criteria indicating that the subject device was as effective as the primary predicate device.

The results of comparative study performed were indicated below.

Section	Requirement	CLEARFIL Universal Bond Quick 2 (Subject device)	CLEARFIL Universal Bond Quick (Primary predicate device)	BeautiBond Xtreme (Predicate device)
Appearance	Yellow or orange transparent liquid No extraneous material	***COMPLIES***	***COMPLIES***	
Easy of application	Easy to apply	***COMPLIES***	***COMPLIES***	
Depth of cure	Equal to or greater than 0.5 mm	***COMPLIES***	***COMPLIES***	
Shear bond strength to bovine enamel	Equal to or greater than 10 MPa	***COMPLIES***	***COMPLIES***	***COMPLIES***
Shear bond strength to bovine dentin	Equal to or greater than 10 MPa	***COMPLIES***	***COMPLIES***	***COMPLIES***
Tensile bond strength to dental ceramic	Equal to or greater than 10 MPa	***COMPLIES***	***COMPLIES***	
Tensile bond strength to metal	Equal to or greater than 17 MPa	***COMPLIES***	***COMPLIES***	
Occlusion dentinal tubules	Dentinal tubules are occluded	***COMPLIES***	***COMPLIES***	
pH	2.4 ± 0.4	***COMPLIES***	***COMPLIES***	

The results indicate that the subject device and the primary predicate device comply with the requirements of the in-house standard. From the above, it can be said that comparative study of the subject device is substantially equivalent to that of the primary predicate device. It also can be said that shear bond strength to bovine enamel/dentin of the subject device is substantially equivalent to that of the predicate device.

Fluoride release testing was performed to validate the substantial equivalence of the subject device with the primary predicate device.
It was concluded that the subject device is substantially equivalent to the primary predicate device.

5-7. Biocompatibility

The subject device is categorized into the external communicating device (tissue/ bone/dentin) and permanent contact device. There is no new ingredient in the subject device.
K-ETCHANT Syringe is categorized into the external communicating device that may contact dentin and whose duration of contact is less than 24 hours.

All ingredients in the subject device have been used in the primary predicate device and the reference device as described in “Section 12: Substantial Equivalence Discussion”.
Regarding these primary predicate device and reference device, there have not been any reported problems or recalls according to the post market adverse event reporting requirements in the US.
Moreover, we already have had 510(k) clearance of K-ETCHANT Syringe (510(k) Number: K133078).

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

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 the reference device.
This submission information including the nonclinical testing provided supports that the subject device is as safe and as effective as the primary predicate device.