May 25, 2021

Tokuyama Dental Corporation
% Keith Barritt
Principal
Fish & Richardson, P.C.
1000 Maine Avenue, S.W., Suite 1000
Washington, District of Columbia 20024

Re: K203760
Trade/Device Name: Tokuyama Universal Bond II
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: March 23, 2021
Received: March 25, 2021

Dear Keith Barritt:

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: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*

K203760

Device Name

TOKUYAMA UNIVERSAL BOND II

Indications for Use *(Describe)*

The TOKUYAMA UNIVERSAL BOND II is indicated for:

- Direct anterior and posterior restorations with light-curing, dual-curing, and self-curing composite materials
- Intraoral repair of composite restorations, porcelain fused to metal, metal, and all-ceramic restorations without an additional primer
- Cementation of indirect restorations and veneers when combined with light-cure, dual-cure, and self-curing resin cements
- Bonding of core build-ups made of core build-up materials
- Bonding of denture resin to metal base, clasp or attachment
- Repair of denture with metal base, clasp or attachment
- Bonding of opaque resin to a metal base in the fabrication of resin-faced crowns

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."

510(k) SUMMARY- K203760
Tokuyama Dental Corporation
TOKUYAMA UNIVERSAL BOND II

Submitter's Name and Address

(i) 510(k) Submitter

Tokuyama Dental Corporation
38-9 Taitou 1-chome, Taitou-ku
Tokyo 110-0016
Japan
Phone: 011-81-3-3835-2261

(ii) 510(k) Submitter Contact

Keith A. Barritt
Fish & Richardson P.C.
1000 Maine Avenue, S.W., Suite 1000
Washington, DC 20024
Phone: (202) 626-6433
Facsimile: (202) 783-2331
Email: barritt@fr.com

(iii) Preparation Date

December 17, 2020

Name of Device

Trade or Proprietary Name:	TOKUYAMA UNIVERSAL BOND II
Common Name:	self-cured dental adhesive
Classification Name:	agent, tooth bonding, resin
Product Code:	KLE
Regulation:	21 CFR 872.3200

Predicate Devices

The TOKUYAMA UNIVERSAL BOND II device (K#203760) is substantially equivalent to Tokuyama's own TOKUYAMA UNIVERSAL BOND device (K#171226). Reference devices to help establish the biocompatibility of a few ingredients are the TOKUYAMA ONE-UP BOND F (K#993917), TOKUYAMA BOND FORCE (K#$070215), and ESTECEM Tokuyama Universal Primer (K#150727). The Scotchbond Universal device (K#110302) is also used as a reference device for performance specifications.

Device Description

The TOKUYAMA UNIVERSAL BOND II device is a two-component self-cured dental adhesive system for both direct and indirect restorations that can be used with self-etch, selective-enamel-etch and total-etch techniques. As a universal adhesive, TOKUYAMA UNIVERSAL BOND II has been designed to be fully compatible with light-cured, self-cured and dual-cured composite materials.

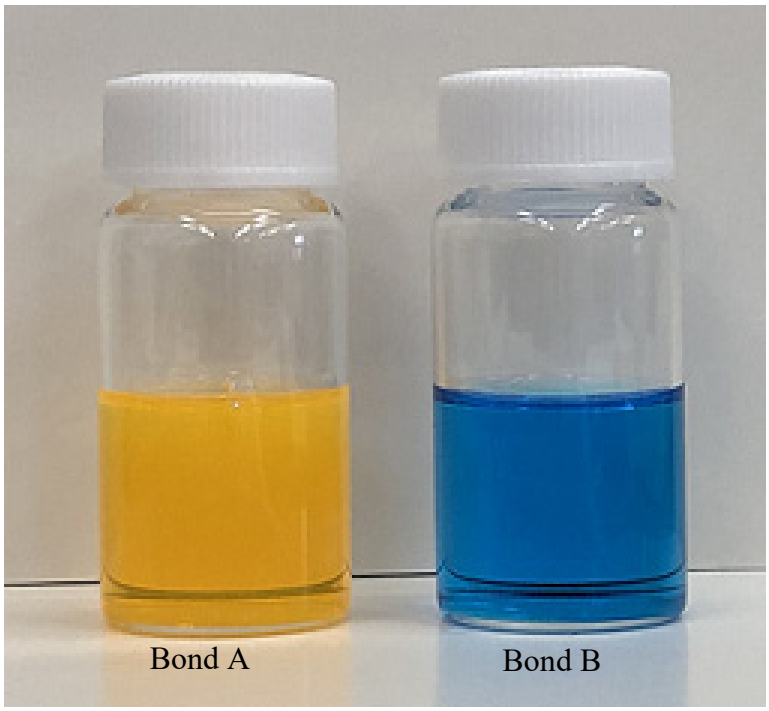
TOKUYAMA UNIVERSAL BOND II contains phosphoric acid monomer, bisphenol A di(2-hydroxy propoxy) dimethacrylate (Bis-GMA), triethylene glycol dimethacrylate (TEGDMA), 2-Hydroxyethyl methacrylate (HEMA), MTU-6 (thiouracil monomer), silane coupling agent, peroxide, borate catalyst, acetone, ethanol and purified water.

Bond A and Bond B are packaged in separate plastic bottles. A group of polymerization agents is contained in the Bond A and Bond B to avoid reaction during storage, and the polymerization reaction begins upon mixing. When the mixture is applied thinly to adherends and concentrated by air-drying, a cured layer is formed by polymerization of methacrylic monomers. The cured layer functions as an adhesive layer for enhancing adhesiveness of polymerization resin to the adherends.

The device improves the bond strength of polymerizable resin material (adhesive resin cement, acrylic resin, and composite resin) to indirect restorative materials such as glass-ceramics (porcelain), oxide-ceramics (zirconia and alumina), metals (precious and non-precious), and resin materials including inorganic filler.

The TOKUYAMA UNIVERSAL BOND device does not come sterilized and is not intended to be sterilized prior to use.

The entire device is depicted below:



Appearance of Bond A and B liquid

Intended Use/Indications for Use

The TOKUYAMA UNIVERSAL BOND II is indicated for:

- Direct anterior and posterior restorations with light-curing, dual-curing, and self-curing composite materials
- Intraoral repair of composite restorations, porcelain fused to metal, metal, and all-ceramic restorations without an additional primer
- Cementation of indirect restorations and veneers when combined with light-cure, dual-cure, and self-curing resin cements
- Bonding of core build-ups made of core build-up materials
- Bonding of denture resin to metal base, clasp or attachment
- Repair of denture with metal base, clasp or attachment
- Bonding of opaque resin to a metal base in the fabrication of resin-faced crowns

Technological Characteristics

The TOKUYAMA UNIVERSAL BOND II device has the same basic technological characteristics in terms of design, material, and chemical composition as the devices identified above. The TOKUYAMA UNIVERSAL BOND II device does not have an energy source. Although the chemical compositions are not identical, the material properties, principles of operation, and performance characteristics of the TOKUYAMA UNIVERSAL BOND II device are comparable to the previously authorized devices identified above, as demonstrated in part by the non-clinical performance bench testing described below.

A comprehensive chart comparing the devices appears below.

Comparison of TOKUYAMA UNIVERSAL BOND II device with the primary predicate and reference devices

	Subject device	Primary predicate	Reference	Difference
Device name	TOKUYAMA UNIVERSAL BOND II	TOKUYAMA UNIVERSAL BOND	Scotchbond Universal (Adhesive EXL 759) [1)]	-
Manufacturer	Tokuyama Dental Corporation	Tokuyama Dental Corporation	3M ESPE AG	-
510(k) No.	K203760	K171226	K110302 [2)]	-
Health Canada licence No.		100487	87883	
Classification name	Agent, Tooth Bonding, Resin	Agent, Tooth Bonding, Resin	Agent, Tooth Bonding, Resin	-
Indications for Use	-Direct anterior and posterior restorations with light-curing, dual-curing, and self-curing composite materials -Intraoral repair of composite restorations, porcelain fused to metal, metal, and all-ceramic restorations without an additional primer -Cementation of indirect restorations and veneers when combined with light-cure, dual-cure, and self-curing resin cements -Bonding of core build-ups made of core build-up materials -Bonding of denture resin to metal base, clasp or attachment -Repair of denture with metal base, clasp or attachment -Bonding of opaque resin to a metal base in the fabrication of resin-faced crowns	The TOKUYAMA UNIVERSAL BOND is indicated for: -Direct anterior and posterior restorations with light-curing, dual-curing, and self-curing composite materials -Intraoral repair of composite restorations, porcelain fused to metal, metal, and all-ceramic restorations without an additional primer -Cementation of indirect restorations and veneers when combined with light-cure, dual-cure, and self-curing resin cements -Bonding of core build-ups made of core build-up materials -Bonding of denture resin to metal base, clasp or attachment -Repair of denture with metal base, clasp or attachment -Bonding of opaque resin to a metal base in the fabrication of resin-faced crowns	-All classes of fillings (according to Black) with light-curing composite or compomer filling materials -Cementation of indirect restorations when combined with RelyX Ultimate Adhesive Resin Cement -Cementation of veneers when combined with RelyX Veneer Cement -Bonding of core build-ups made of light-curing composite or core build-up materials -Bonding of dual-cure cements and core build-up materials and self-cure composites when combined with Scotchbond Universal DCA -Repair of composite or compomer fillings -Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer -Root surface desensitization -Sealing of cavities prior to cementation of amalgam restorations -Sealing of cavities and preparation of tooth stumps prior to temporary cementation of indirect restorations -Bonding of fissure sealants -Protective varnish for glass ionomer fillings	Similar The Indications for Use of subject device is within that of the predicate and the reference devices.
Component	Consisting of Bond A and Bond B in separate bottles	Consisting of Bond A and Bond B in separate bottles	Bottle or unit-dose	Similar The subject device uses a bottle that is slightly different from the one used for the predicate device.

Principle of operation		The device functions as an adhesive layer for enhancing an adhesiveness of polymerizable resin to adherends, and is used by applying on the surface of adherends.	The device functions as an adhesive layer for enhancing an adhesiveness of polymerizable resin to adherends, and is used by applying on the surface of adherends.	The device functions as an adhesive layer for enhancing an adhesiveness of polymerizable resin to adherends, and is used by applying on the surface of adherends.	Similar
Material [3)]		- Phosphoric acid monomer - Bisphenol A di(2-hydroxy propoxy) dimethacrylate (Bis-GMA) - Triethylene glycol dimethacrylate (TEGDMA) - 2-Hydroxyethyl methacrylate (HEMA) - MTU-6 (thiouracil monomer) - Silane coupling agent - Peroxide - Borate catalyst - Acetone - Etanol - Water	- Phosphoric acid monomer - Bisphenol A di(2-hydroxy propoxy) dimethacrylate (Bis-GMA) - Triethylene glycol dimethacrylate (TEGDMA) - 2-Hydroxyethyl methacrylate (HEMA) - MTU-6 (thiouracil monomer) - Silane coupling agent - Peroxide - Borate catalyst - Acetone - Isopropnanol - Water	- 2-HYDROXYETHYL METHACRYLATE - BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BIS-GMA) - 2-PROPENOIC ACID, 2-METHYL-, REACTION PRODUCTS WITH 1,10-DECANEDIOL AND PHOSPHOROUS OXIDE (Phosphoric acid monomer) - ETHANOL - 2-PROPENOIC ACID, 2-METHYL-, 3-(TRIMETHOXYSILYL)PROPYL ESTER, REACTION PRODUCTS WITH VITREOUS SILICA - COPOLYMER OF ACRYLIC AND ITACONIC ACID - CAMPHORQUINONE - DIMETHYLAMINO BENZOAT(-4) - (DIMETHYLAMINO)ETHYL METHACRYLATE	Similar The subject device contains a phosphate monomer, methacrylic monomer, adhesive compound to prosthetic materials, initiator, catalyst and solvent as with the predicate device.
Physical property: tensile bond strength [4)]	Enamel [MPa]	≥ 12	≥ 12	-	Similar The subject device has the same in-house specification as the predicate device..
	Dentin [MPa]	≥ 10	≥ 10	-	
	Metal [MPa]	≥ 12	≥ 12	-	
	Porcelain [MPa]	≥ 10	≥ 10	-	
	Zirconia [MPa]	≥ 10	≥ 10	-	
	Resin material including inorganic filler * [MPa]	≥ 10	≥ 10	-	
Sterilization		Non-sterile	Non-sterile	Non-sterile	Identical
Shelf life		2 years at a temperature between 0-25ºC (32-77Fº)	3 years at a temperature between 0-10ºC (32-50Fº)	2 years at a temperature between 0-25ºC (32-77Fº)	Similar The shelf life of the subject device is within that of the predicate and the reference devices.

1) According to the brochure "A Collection of Scientific Facts - Scotchbond Universal Adhesive", Scotchbond Universal and Adhesive EXL 759 are the same product.

2) 510(k) number of Adhesive EXL 759

3) Materials of Scotchbond Universal Adhesive are described in the SDS.

4) In-house specification

Non-clinical Testing

Non-clinical testing of the following physical properties was conducted on the TOKUYAMA UNIVERSAL BOND II device.

Tensile bond strength to enamel: Testing was conducted pursuant to Section 5.1 of ISO/TS 11405:2015.

Tensile bond strength to dentin: Testing was conducted pursuant to Section 5.1 of ISO/TS 11405:2015.

Tensile bond strength to metal: Testing was conducted pursuant to Section 5.1 of ISO/TS 11405:2015.

Tensile bond strength to porcelain: Testing was conducted pursuant to Section 5.1 of ISO/TS 11405:2015.

Tensile bond strength to zirconia: Testing was conducted pursuant to Section 5.1 of ISO/TS 11405:2015.

Tensile bond strength to resin material including inorganic filler: Testing was conducted pursuant to Section 5.1 of ISO/TS 11405:2015.

The working time of the device was evaluated by confirming whether the device was cured after three minutes.

The precise formulation of the device is confidential. Substantial biocompatibility testing was evaluated in accordance with ISO 10993-1:2009.

The device was also designed following principles of ISO 14971 Second Edition 2007-03-01 Medical Devices – Application of Risk Management to Medical Devices

Clinical Testing

There were no clinical tests performed for the TOKUYAMA UNIVERSAL BOND II device.

Conclusions from Testing

Based on the non-clinical testing conducted of the physical properties and the biocompatibility testing of the TOKUYAMA UNIVERSAL BOND II device, it is concluded that the TOKUYAMA UNIVERSAL BOND II device is substantially equivalent to the primary predicate device identified above.