May 22, 2023

Mediclus Co., LTD.
℅ Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave
Ste 160
Irvine, California 92612

Re: K230465
Trade/Device Name: Hi-Bond Universal
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE, EBF, LBH
Dated: February 21, 2023
Received: February 21, 2023

Dear Priscilla Chung:

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 -S

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)*
K230465

Device Name
Hi-Bond Universal

Indications for Use *(Describe)*

1. all direct restorations
2. all indirect restorations
3. intra-oral repairs (i.e. repair of any fixed dental prosthesis containing zirconia, alumina, metals, glass ceramics, tooth structure, and composites)
4. desensitizing/sealing of tooth structure
5. protective varnish for glass ionomer fillings
6. priming of enamel for orthodontic use

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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K230465 - 510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: ___Feb 21, 2023___

1. Applicant / Submitter:

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2. Submission Correspondent:

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3. Device:

Proprietary Name:	Hi-Bond Universal
Common Name:	Dental adhesive material
Classification Name:	Agent, Tooth Bonding, Resin
Classification:	Class II, 21 CFR 872.3200
Classification Product Code:	KLE

4. PrimaryPredicate Device:

All-Bond Universal w/ BAC (K161051) by Bisco, Inc.

5. Device Description:

The Hi-Bond Universal is a light-curing dentin adhesive system composed of several resin monomers, inorganic fillers, polymerization-related initiators and accelerators, ethyl alcohol, and antioxidants. The Hi-Bond Universal is a light-curing type dental adhesive offering etching, priming, and bonding at once. The Hi-Bond Universal is packaged in a bottle made of polyethylene and polypropylene, and then packaged in a box.

6. Indications for Use:

1. all direct restorations
2. all indirect restorations
3. intra-oral repairs (i.e. repair of any fixed dental prosthesis containing zirconia, alumina, metals, glass ceramics, tooth structure, and composites)
4. desensitizing/sealing of tooth structure
5. protective varnish for glass ionomer fillings
6. priming of enamel for orthodontic use

7. Performance Data (Non-Clinical):

The following tests were performed on the subject device and the test results support that the subject device is substantially equivalent to the predicate devices.

- Appearance
- Volume Accuracy
- Packing
- Film Thickness in accordance with ISO 4049
- Sensitivity to ambient light in accordance with ISO 4049
- Polymerization depth in accordance with ISO 4049
- Adhesive strength (Dentin, self-etch) in accordance with ISO 11405
- Adhesive strength (Enamel, total-etch) in accordance with ISO 11405
- pH
- Dentinal tubule blockage

8. Substantial Equivalence

8.1. Comparison Chart

	Subject Device	Predicate Device
510(K) Number	-	K161051
Device Name	Hi-Bond Universal	All-Bond Universal w/ BAC
Manufacturer	MEDICLUS CO., LTD.	Bisco, Inc.
Product Code	KLE	KLE

Design			
Indications for Use		1. all direct restorations 2. all indirect restorations 3. intra-oral repairs (i.e. repair of any fixed dental prosthesis containing zirconia, alumina, metals, glass ceramics, tooth structure, and composites) 4. desensitizing/sealing of tooth structure 5. protective varnish for glass ionomer fillings 6. priming of enamel for orthodontic use	1. all direct restorations 2. all indirect restorations 3. intra-oral repairs (i.e. repair of any fixed dental prosthesis containing zirconia, alumina, metals, glass ceramics, tooth structure, and composites) 4. desensitizing/sealing of tooth structure 5. protective varnish for glass ionomer fillings 6. priming of enamel for orthodontic use
Method of polymerization		Light Cured	Light Cured
Material Composition		- 10-Methacryloyl-oxydecyl dihydrogen phosphate - 2-Hydroxyethyl methacrylate - Bisphenol A glycerolate Dimethacrylate - Water - Ethanol - Ethyl 4-dimethylaminobenzoate	- 10-Methacryloyl-oxydecyl dihydrogen phosphate - 2-Hydroxyethyl methacrylate - Bisphenol A diglycidylmethacrylate - Water - Ethanol
Method of application		Single component adhesive	Single component adhesive
Physical / Mechanical Property Comparison	Film thickness	12µm	3.4µm
	Etch Methods	Self-etch and total-etch	Self-etch and total-etch

8.2. Substantial Equivalence Discussion

The subject device has the same indications for use statement as well as technological characteristics as the predicate device (K161051, All-Bond Universal w/ BAC). Both devices are a single component system offering self-etching and total etching. The difference is in chemical compositions; however, the test results of biocompatibility and performance tests supports that the subject device is substantially equivalent to the predicate device.

9. Conclusion:

Based on the information submitted herein, MEDICLUS CO., LTD. concludes that the Hi-Bond Universal is substantially equivalent to the predicate device.