March 3, 2023

Meta Biomed Co., LTD.
℅ April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

Re: K230009
Trade/Device Name: EZ Bond Universal
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: January 3, 2023
Received: January 3, 2023

Dear April Lee:

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)*
K230009

Device Name
EZ Bond Universal

Indications for Use *(Describe)*

- All classes of fillings (according to Black) with light-curing composite or compomer filling materials
- Repair of composite resin or compomer fillings
- Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer
- Protective varnish for glass ionomer fillings

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

Submitter
META BIOMED CO., LTD.
Suk Song Oh
270, Osongsaengmyeong 1-ro, Osong-eup,
Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,
South Korea
Email: ef1459@metabiogw.bizmeka.com
Phone: +82-43-230-8841
Fax: +82-43-217-1983

Official Correspondent
Withus Group Inc
April Lee
106 Superior,
Irvine, CA 92620
USA
Email: withus6664@gmail.com
Phone: 1-909-274-9971
Fax: 1-909-460-8122

Device Information

- Trade Name: EZ Bond Universal
- Classification Name: agent, tooth bonding, resin
- Common Name: Resin Tooth Bonding Agent
- Product Code: KLE
- Panel: Dental
- Regulation Number: 21 CFR 872.3200
- Device Class: Class II
- Date prepared: 02/28/2023

Predicate Devices:

- K110302, ADHESIVE EXL-759 by 3M ESPE AG

Device Description

EZ Bond Universal, manufactured by Meta Biomed, is classified as a Resin tooth bonding agent (21 C.F.R. §872.3200). EZ Bond universal is a single-bottle solution. Depending on the indication, the adhesive can be used for direct and indirect restorations with light cured composites in a "self-etching" procedure, "total-etching" procedure or" selective-etching" procedure. EZ Bond Universal is methacrylate-based restoratives, cement and sealant materials to dentin, enamel, glass ionomer and various indirect restorative substrates (glass ceramics, alumina and zirconia) without an extra primer step.

Indication for Use

- All classes of fillings (according to Black) with light-curing composite or compomer filling materials
- Repair of composite resin or compomer fillings
- Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer
- Protective varnish for glass ionomer fillings

Non-clinical Testing

The subject device was tested to evaluation its safety and effectiveness according to the following standards:

- Biocompatibility Tests according to ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2017.
- Performance tests such as Film thickness, Sensitivity to ambient Light, Bond strength-Dentine, Bond strength-enamel, Fine leakage according to ISO 4049:2019, ISO 29022:2013, ISO/TC 11405:2015
- Shelf Life tests according to ISO 4049:2019, ISO 29022:2013.

Summary of Technological Characteristics:

The subject device and predicate device have same intended use and principle of operation and similar technological characteristics such as capacity, film thickness, Sensitivity to Ambient Light, depth of cure, bond strength and shelf life.

The difference between the subject and predicate device is solubility. As the solubility value of the subject device is within the range that ISO 4049:2009, it doesn't affect safety and effectiveness.

	Subject Device	Predicate Device
Manufacturer	Meta Biomed Co., Ltd.	3M ESPE AG
Device Name	EZ Bond Universal	ADHESIVE EXL-759
510(k) Number	NA	K110302
Common Name	Resin Tooth Bonding Agent	Resin Tooth Bonding Agent
Product Code	KLE	KLE
Regulation Number	21 CFR 872.3200	21 CFR 872.3200
Indications for Use	• All classes of fillings (according to Black) with light-curing composite or compomer filling materials • Repair of composite resin or compomer fillings • Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer • Protective varnish for glass ionomer fillings	• 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 Single Bond 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 • Surface treatment of porcelain, ceramics (including glass ceramics, zirconia and alumina), metal and composite.
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.
Raw Material	-MDP Phosphate Monomer -HEMA -Ethanol	-MDP Phosphate Monomer -HEMA -Ethanol
Film thickness	4 ㎛	10.6 ㎛
Sensitivity to Ambient	Material remained physically homogeneous.	Material remained physically homogeneous.
Bond strength, Dentine	23.2 Mpa	35.8 Mpa
Bond strength, enamel	23.7 Mpa	26.4 Mpa
Shelf Life	2 Years	2 Years

Conclusion:

Metabiomed Co., Ltd believes that EZ Bond Universal is substantially equivalent to currently legally marketed product. Product based on comparison of similar intended use and technologies tougher with the non-clinical performance testing. Any differences do not raise different questions of safety and effectiveness than the predicate, nor do they affect the safety or effectiveness of the subject device. These differences therefore, do not render the new device NSE in comparison to the predicate.