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

August 29, 2018

Re: K180802
Trade/Device Name: Meta P&Bond
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: March 21, 2018
Received: March 28, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K180802

Device Name
Meta P&Bond

Indications for Use *(Describe)*

- A dental adhesive formulated to adhesively bond to hard tissues of the oral cavity, enamel and dentin
- Dentin-enamel primer/bonding agent for direct composite restorations
- Indirect composite restorative luting system
- Porcelain veneer luting system
- Bonding composite to composite
- Bonding composite to metal/amalgam
- Adhesive amalgam 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.

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510(k) Summary

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Device Information

- Trade Name: Meta P&Bond
- Classification Name: agent, tooth bonding, resin
- Product Code: KLE
- Panel: Dental
- Regulation Number: 21 CFR 872.3200
- Device Class: Class II
- Date prepared: 08/22/2018

Predicate Devices:

- K081913, Meta P&Bond manufactured by Meta Biomed Co., Ltd.

Device Description

Meta P&Bond is a wet bond adhesive system that is activated by visible light curing. This bonding agent is one-step for priming and bonding. It is formulated to adhesively bond to hard surfaces of the oral cavity, namely enamel and dentin, for use with dental cements. It is useful as a primer for use with other methacrylate cements. It is intended to be painted on the interior of a prepared cavity or surface of a tooth to improve retention of a restoration such as a filling or crown. It also is useful as a prime and bonder for porcelain veneer luting, bonding composite to composite, and composite to metal/amalgam.
Meta P&Bond is packaged with Microbrush accessories.

Indication for Use

- A dental adhesive formulated to adhesively bond to hard tissues of the oral cavity, enamel and dentin
- Dentin-enamel primer/bonding agent for direct composite restorations
- Indirect composite restorative luting system
- Porcelain veneer luting system
- Bonding composite to composite
- Bonding composite to metal/amalgam
- Adhesive amalgam restorations

Non-clinical Testing

The subject device was tests in accordance to the following standards:

- Biocompatibility Tests according to ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2006.

- Performance tests such as visual, capacity, package, film thickness, solubility, sensitivity to ambient light, Depth of cure, Bone strength (Dentin, Enamel) according to ISO 4049:2009.

- Shelf Life tests according to ISO4049:2009.

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.	META BIOMED CO., LTD.
Device Name	Meta P&Bond	Meta P&Bond
510(k) Number	K180802	K081913
Classification Name	Resin tooth bonding agent	Resin tooth bonding agent
Product Code	KLE	KLE
Regulation Number	21 CFR 872.3200	21 CFR 872.3200
Intended Use	Identical	• A dental adhesive formulated to adhesively bond to hard tissues of the oral cavity, enamel and dentin • Dentin-enamel primer/bonding agent for direct composite restorations • Indirect composite restorative luting system • Porcelain veneer luting system • Bonding composite to composite

		• Bonding composite to metal/amalgam • Adhesive amalgam restorations
Principle of operation	Meta P&Bond adhesive system is wet bond adhesive system that is activated by visible light curing. This bonding agent is one step for priming and bonding.	Meta P&Bond adhesive system is wet bond adhesive system that is activated by visible light curing. This bonding agent is one step for priming and bonding.
Capacity	1.37%	2.15%
Film thickness	2 µm	1 µm
Solubility	1.4 µg/mm^2	7.5 µg/mm^2
Sensitivity to Ambient Light	Material remained physically homogeneous	Material remained physically homogeneous
Depth of Cure	2.9 mm	3.53 mm
Bone Strength, Dentine	17 MPa	10 MPa
Bone Strength, Enamel	31 MPa	30.76 MPa
Shelf Life	2 Years	2Years

Conclusion:

Metabiomed Co., Ltd believes that Meta P&Bond is substantially equivalent to the currently legally marketed product based on similar intended use, physical, chemical and mechanical properties. Any differences do not raise different questions of safety and effectiveness than the predicate. These differences therefore, do not render the new device NSE in comparison to the predicate.