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

May 15, 2018

Re: K171449
Trade/Device Name: Metacem
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: February 7, 2018
Received: February 14, 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*
K171449

Device Name
Metacem

Indications for Use *(Describe)*
Adhesive cementation of:
- Crown & Bridges (Ceramic, Composite, Porcelain, Metal)
- Inlay / Onlay cementation
- Bonding for porcelain veneers
- Endodontic posts cementation
- Core build up

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.

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510(k) Summary

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Device Information

- Trade Name: Metacem
- Classification Name: cement, dental
- Product Code: EMA
- Panel: Dental
- Regulation Number: 21 CFR 872.3275
- Device Class: Class II
- Date prepared: 05/08/2018

Predicate Devices:

The subject device is substantially equivalent to the following predicate devices:

- K081913, Metacem manufactured by Meta Biomed Co., Ltd.

General Description

Metacem is a high strength, permanent visible light cured (VLC), dual cured or self-cured resin cement for use with dentin/enamel adhesive prime and bone systems, to adhesively bond and lute indirect restorations to tooth structure. Metacem consists of a methacrylate base paste and catalyst paste which in use are instantly mixed from a dual syringe of form a dual-cured cement. This mixed version of the cement will self-cure or can be light cured, or both. The dual cure is effective for dark shade, thick or opaque cementation.

Indication for Use

Adhesive cementation of:

- Crown & Bridges (Ceramic, Composite, Porcelain, Metal)
- Inlay / Onlay cementation
- Bonding for porcelain veneers
- Endodontic posts cementation
- Core build up

Comparison of technological Characteristics with Predicate Devices:

	Specification	Subject Device	Primary Predicate Device
Manufacturer	-	META BIOMED CO., LTD.	META BIOMED CO., LTD.
Device Name	-	Metacem	Metacem
510(k) Number	-	NA	K081913
Classification Name	-	Dental Cement	Dental Cement
Product Code	-	EMA	EMA
Regulation Number	-	21 CFR 872.3275	21 CFR 872.3275
Indications for Use	-	Adhesive cementation of: • Crown & Bridges (Ceramic, Composite, Porcelain, Metal) • Inlay / Onlay cementation • Bonding for porcelain veneers • Endodontic posts cementation • Core build up	
Intended Use	-	Metacem is intended for use in the cementing or fixation of restorations and appliances such as inlays, onlays, veneers, crowns, bridges and posts classed by Type 2, Class 3 according to ISO 4049.	
General Composition	-	• Bis-GMA [Bisphenol A Glycerolate (1glycerol/Phenol)dimethacrylate] • TEGDMA [Tri(ethylene glycol)dimethacrylate] • Camphorquinone • DEPT [2,2'-(P-Tolyimino)diethanol]	
Film thickness	ISO 4049:2009	26.4 ㎛	0.034 ± 0.006 mm (34 ㎛)

Working time	ISO 4049:2009	homogeneous	2 min 32 sec
Setting time	ISO 4049:2009	A1: 3min 14sec A3: 3min 04sec B2: 3min 57sec OP: 3min 34sec TL: 2min 28sec	5 min 17 sec
Flexular strength	ISO 4049:2009	120.5 MPa	99 ± 16.1 MPa
Water sorption solubility	ISO 4049:2009	Water sorption : 14.0 ㎍/㎣ Solubility : 0.5 ㎍/㎣	Water sorption : 29.31 ± 6.81 ㎛/㎣ Solubility : 2.33 ± 1.30 ㎛/㎣
Radio-opacity	ISO 4049:2009	2.3 mm	2.33 ± 0.34 mm
Color Color stability	ISO 4049:2009	Consistency	Consistency
Tensile Bond Strength	ISO 11405	Enamel: 27.5 MPa Dentin: 6.1 Mpa	Enamel: 28.3 Mpa Dentin: 7.6 Mpa
Shear Bond Strength	ISO29022:2013	Dentine: 3MPa Enamel: 15MPa	N/A
Shelf life	-	2 years	2 years

Non-clinical Testing

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

- Biocompatibility Tests according to ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2006.
- Performance tests such as film thickness, working time, setting time, Flexular strength, water sorption/solubility, radio-opacity, and color/color stability according to ISO 4049:2009.
- Shelf Life tests according to ISO4049:2009.
- Shear Bond Strength tests for dentin and enamel according to ISO 11405:2015.

Conclusions

The subject device is similar to the predicate devices in that they are all dual-curing, radio-opaque and self-adhesive resin cements to be used for permanently cementing restorations.

The subject device and the predicate devices has substantially equivalent of indications for use, shelf life, physical and mechanical properties. As depicted above, the values for the flexular strength between the subject device and predicate device demonstrate higher values for the subject device. This difference does not affect the substantial equivalence.

The subject device is different from the predicate devices in that it contains the same key biocompatible ingredients, but in different proportions. The biocompatibility test report supports this difference and it does not affect the substantial equivalence.