July 3, 2019

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

Re: K190724
Trade/Device Name: MD-Temp Plus
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: April 5, 2019
Received: April 10, 2019

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,

Srinivas Nandkumar, PhD
Acting Assistant Director
DHT1B: Division of Dental 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)*
K190724

Device Name
MD-Temp Plus

Indications for Use *(Describe)*
For fabrication of temporary fillings and other temporary prosthetics for use until the permanent prosthetic is ready for insertion. intended to temporarily restore carious lesions or structural defects in teeth. Intended for use in cavities, Class I, II, III, IV (inlays and onlays).

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: MD-Temp Plus
- Classification Name: Crown And Bridge, Temporary, Resin
- Product Code: EBG
- Panel: Dental
- Regulation Number: 21 CFR 872.3770
- Device Class: Class II
- Date prepared: 06/26/2019

Predicate Devices:

Primary Predicate

- K061530, MD-TEMP manufactured by Meta Biomed Co., Ltd.

Device Description

MD-Temp Plus is used for temporary filling material. It is supplied in a 20, 30 or 40g jar in either white (tooth-like) or pink (gum-like), and individually boxed. It is intended primarily as a temporary filling material for most cavities or damages but may be used by the dentist for other temporary restorations. MD-Temp plus is water-based temporary filling materials used for part of a tooth or multiple teeth. The curing reaction is the hydration reaction of the gypsum, and the semi-gypsum is cured as it is exposed to saliva or water in the oral cavity.

Indication for Use

For fabrication of temporary fillings and other temporary prosthetics for use until the permanent prosthetic is ready for insertion. intended to temporarily restore carious lesions or structural defects in teeth. Intended for use in cavities, Class I, II, III, IV (inlays and onlays).

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 appearance, weight, packaging
- Shelf Life tests according to the ASTM F1980
- Compressive Strength testing according to ISO 3107: 2011
- Setting time testing according to ISO 3107: 2011
- Compared Flexural Strength Test according to the ISO 4049:2009
- Compared Tensile Strength Test according to the ANSI/ADA 27:1977

Summary of Technological Characteristics:

The subject device and predicate device have same Indications for use and principle of operation and similar technological characteristics and testing standards.

Some technological characteristics such as setting time and compressive strength are different between the subject and primary predicate, however, it is to improve the device's performance. Both test results are within the range of the test standards and it doesn't affect the safety and effectiveness.

	Subject Device	Primary Predicate
Manufacturer	META BIOMED CO., LTD.	META BIOMED CO., LTD.
Device Name	MD-Temp Plus	MD-Temp
510(k) Number	NA	K061530
Classification Name	Crown And Bridge, Temporary, Resin	Crown And Bridge, Temporary, Resin
Product Code	EBG	EBG
Regulation Number	21 CFR 872.3770	21 CFR 872.3770
Indications for Use	For fabrication of temporary fillings and other temporary prosthetics for use until the permanent prosthetic is ready for insertion. intended to temporarily restore carious lesions or structural defects in teeth. Intended for use in cavities, Class I, II, III, IV (inlays and onlays).	For fabrication of temporary fillings and other temporary prosthetics for use until the permanent prosthetic is ready for installation. Intended to restore carious lesions or structural defects in teeth temporarily. Intended for use in cavities Classes I, II, III, IV (inlays and onlays) and as a restorative material for veneers, crowns, and bridges.

Principle of operation	The main curing reaction of temporary filling materials is represented by the hydration reaction of gypsum.	The main curing reaction of temporary filling materials is represented by the hydration reaction of gypsum.
Material Composition	-Vinyl Chloride Vinyl Acetate Copolymer -Bis(2-ethylhexyl) Adipate -Zinc Oxide -Calcium Sulfate Hemihydrate -Menthol Oil -D&C Red 6	- Polyvinyl acetate - Zinc oxide - Zinc sulfate - Ethanol - Dye (Red)
Setting Time	27 min	55 min
Compressive Strength	2.2 MPa	6.5 MPa
Acid soluble arsenic contents	Not detected	0.075
Shelf Life	3 years	2 years
Performing Testing	Tested according to ISO 3107	Tested according to ISO 3107
Biocompatibility Testing	Testing according to ISO-10993-1; -5; -10; -11	Testing according to ISO-10993-1; -5; -10; -11

- Similarities

The subject device and the predicate device have the same indications for use, principle of operations and were tested in accordance with the same testing standards such as ISO 3107 and ISO10993.

- Differences

1. Material Composition

Compared to the primary predicate, some materials of the subject device have been changed as following:

Ingredients from Primary predicate	Ingredients from Subject device	Functions in the devices (Equivalent)
Polyvinyl acetate	Vinyl Chloride - Vinyl Acetate Copolymer	Viscosity modifier
Ethanol	Bis(2-ethylhexyl) Adipate	Diluent
Zinc oxide	Zinc oxide	Filler
Zinc sulfate	Calcium Sulfate hemihydrate	Curing material

The raw materials are different between two devices but their roles and functions are the same. Therefore, overall, the raw materials of two devices are similar.

2. Setting Time and Compressive Strength

Performance characteristics have changed to improve setting time and compressive strength. This difference in performance doesn't affect any safety and effectiveness in clinical practice.

3. Shelf Life

The shelf life of the subject device is 3 years and the shelf life of the predicate device is 2 years.

4. Indications for Use

Even though the indications for use of our subject device and predicate device are different, it doesn't affect product's substantial equivalence since the indications of the subject device is in the range of the indications of the predicate device.

In conclusion, it can be regarded as equivalent when the indications for use, raw materials, working principle and performance are compared.

Conclusion:

The subject and predicate device are similar in indications for use and intended use. After testing for safety and function Meta Biomed Co., Ltd concludes that the improvements to function in setting time and compressive strength do not introduce any new issues and the subject device is substantially equivalent to the predicate device.