June 30, 2021

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

Re: K210904
Trade/Device Name: Metapaste Plus
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: March 15, 2021
Received: March 26, 2021

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210904

Device Name
Metapaste Plus

Indications for Use *(Describe)*

Metapaste Plus is a biocompatible root canal filling used for the temporary filling of root canals after endodontic surgery.
Metapaste Plus can be used on its own and for vital pulpotomy in deciduous teeth.
Metapaste Plus is intended for use by qualified healthcare personnel trained in its 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.

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K210904 510(k) Summary

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Device Information

- Trade Name: Metapaste Plus
- Classification Name: Resin, Root Canal Filling
- Product Code: KIF
- Panel: Dental
- Regulation Number: 21 CFR 872.3820
- Device Class: Class II
- Date prepared: 03/15/2021

Predicate Devices:

Primary Predicate

- K032605, Metapaste by Meta Biomed Co., Ltd.

Device Description

Metapaste Plus is a water-based calcium hydroxide paste material for root canal temporary filling. It is pre-mixed in a syringe for convenient delivery in the root canal. When applied to root canal, it is alkaline by calcium hydroxide. The state of the treatment can be confirmed by the radiopacity of barium sulfate contained. Also, it is water-soluble and easy to remove.

Indication for Use

Metapaste Plus is a biocompatible root canal filling used for the temporary filling of root canals after endodontic surgery. Metapaste Plus can be used on its own and for vital pulpotomy in deciduous teeth. Metapaste Plus is intended for use by qualified healthcare personnel trained in its use.

Summary of Technological Characteristics:

	Subject Device	Predicate Device
Manufacturer	Meta Biomed Co., Ltd.	Meta Biomed Co., Ltd.
Device Name	Metapaste Plus	Metapaste
510(k) Number	NA	K032605
Classification Name	resin, root canal filling	resin, root canal filling
Product Code	KIF	KIF
Regulation Number	21 CFR 872.3820	21 CFR 872.3820
Indications for use	Metapaste Plus is a biocompatible root canal filling used for the temporary filling of root canals after endodontic surgery. Metapaste Plus can be used on its own and for vital pulpotomy in deciduous teeth. Metapaste Plus is intended for use by qualified healthcare personnel trained in its use.	Metapaste is a biocompatible root canal sealer used for the temporary filling of root canals after endodontic surgery. Metapaste can be used on its own and for vital pulpectomies in deciduous teeth. Metapaste is intended for use by qualified healthcare personnel trained in its use.
Raw Material	Calcium hydroxide Barium sulfate Aluminum oxide Titanium oxide Polyethylene glycol Dihydrogen oxide	Calcium hydroxide Barium sulfate Polypropylene glycol
Principle of Operation	Metapaste Plus is a biocompatible root canal sealer used for the temporary filling of root canals after endodontic surgery.	Metapaste is a biocompatible root canal sealer used for the temporary filling of root canals after endodontic surgery.
Performance Standard Conformance	Conformed to ISO 6876	Conformed to ISO 6876
Flowability	21mm	12mm
Radio-opacity	3.1mm	3.4mm
Biocompatibility	Yes	Yes
Sterility	Non-sterile	Non-sterile
Shelf Life	2 years	2 years

The subject device and the primary predicate have the similar indications, principle of operation, technological characteristics and materials. They encompass the same range of physical and chemical properties. The subject device and predicate devices are packaged in similar material and use similar methods of application.

Compared to the primary predicate, Indications for Use, flowability, Radio-opacity and material of the subject device are different.

1) Indications for Use

Metapaste Plus	Metapaste (K032605)	Discussion
Metapaste Plus is a biocompatible root canal filling used for the temporary filling of root canals after endodontic surgery. Metapaste Plus can be used on its own and for vital pulpotomy in deciduous teeth. Metapaste Plus is intended for use by qualified healthcare personnel trained in its use.	Metapaste is a biocompatible root canal sealer used for the temporary filling of root canals after endodontic surgery. Metapaste can be used on its own and for vital pulpectomies in deciduous teeth. Metapaste is intended for use by qualified healthcare personnel trained in its use	subject device (Metapaste plus) and predicate device (Metapaste) are temporary root canal filling materials. The Indication for Use of subject device (Metapaste Plus) and predicate device (Metapaste) has same contents. In the Metapaste Plus Indication for Use, there is content of pulpotomy that is not found in Indication of use of Metapaste. It is a technique commonly used of temporary root canal fillings and as such does not affect the equivalence of Indication of subject and predicate devices.

2) The flowability between the subject and primary predicate is different; however, the flow of dental root canal filling material shall be more than 17mm in accordance with ISO 6876: 2012 test method, which is the subject device's flowability value meet the ISO 6876 requirements. Therefore, this difference doesn't impact the clinical performance of the product and substantial equivalence.
3) The Radio-opacity between the subject and primary predicate is different; however, the Radio-opacity of dental root canal filling material shall have a radio opacity equivalent to not less than 3 mm of aluminium in accordance with ISO 6876: 2012 test method, which is the subject device's Radio-opacity value meet the ISO 6876 requirements. Therefore, this difference doesn't impact the clinical performance of the product and substantial equivalence.
4) The raw materials of subject device and the predicate device have a little difference in specific components and their composition. However, both products belong to calcium hydroxide paste. demonstrating their clinical safety and the biocompatibility of subject device has been proved by performing tests required for evaluating its biocompatibility in accordance with ISO10993-1. For this reason, although there is difference of raw materials between subject device and predicate device, it does not affect the clinical safety of subject device.

Non-clinical Testing

The following testing was conducted on our subject device:

- Performance testing of Appearance, Weight, Packaging according to Manufacturer standard.
- Performance testing of Flowability and Radio-opacity according to ISO 6876:2012.
- Biocompatibility Tests according to EN ISO 10993-1:2009, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-10:2013, EN ISO 10993-11:2017.
- Shelf Life test: Manufacturer standard tests (Appearance, Packaging), ISO 6876:2012 tests (Flowability, Radio-opacity)

Conclusion:

Based on documentation supplied with this submission, conclusions drawn from the testing results demonstrate that the subject device is substantially equivalent to our legally marketed predicate device.