April 14, 2021

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

Re: K202617
Trade/Device Name: Metapex Plus
Regulation Number: 21 CFR 872.3820
Regulation Name: Root canal filling resin
Regulatory Class: Class II
Product Code: KIF
Dated: April 13, 2021
Received: April 13, 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 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)*
K202617

Device Name
Metapex Plus

Indications for Use *(Describe)*
Metapex Plus is a calcium hydroxide paste with iodoform, used as a temporary root canal filling material.
• Application : Root canal filling material/Apexification and hard tissue formation/Apexogensis

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

Submitter
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Device Information

- Trade Name: Metapex Plus
- Classification Name: Resin, Root Canal Filling
- Product Code: KIF
- Panel: Dental
- Regulation Number: 21 CFR 872.3820
- Device Class: Class II
- Date prepared: 04/09/2021

Predicate Devices:

Primary Predicate

- K182625, Diapex Plus by DiaDent Group International

Reference Devices:

- K973667, Vitapex Pre-Loaded Dental Syringe by Neo Dental Chemical Products Company, Ltd.

Device Description

This product is a calcium hydroxide paste material that is temporarily filled into the root canal.
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 iodoform contained.
Metapex Plus is used for patients of all ages requiring root canal treatment.

Indication for Use

Metapex Plus is a calcium hydroxide paste with iodoform, used as a temporary root canal filling material.

- Application: Root canal filling material/Apexification and hard tissue formation/Apexogensis

Summary of Technological Characteristics:

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, the flowability Radiopacity, and material are different with the subject device.
however, the flow of dental root canal filling material shall be more than 17mm in accordance with ISO 6876: 2012 test method and 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.
Also, the Radio-opacity of dental root canal filling material shall have a radio opacity equivalent to not less than 3 mm of aluminum in accordance with ISO 6876: 2012 test method and 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.

Compared to the predicate devices, some of minor ingredients are different with the subject device. However, the main ingredients of Calcium hydroxide and Iodoform are same and by performing the biological evaluation and testing, biological safety of the subject device was proved and it demonstrates the clinical performance and safety of the subject device. Therefore, although there is difference of raw materials between subject device and predicate devices, it does not affect the clinical performance and safety and the devices are substantial equivalent.

	Subject Device	Predicate Device	Reference Device
Manufacturer	META BIOMED CO., LTD.	DiaDent Group International	NEO DENTAL CHEMICAL PRODUCTS CO., LTD.
Device Name	Metapex Plus	Diapex Plus	Vitapex
510(k) Number	NA	K182625	K973667
Classification Name	resin, root canal filling	resin, root canal filling	resin, root canal filling
Product Code	KIF	KIF	KIF
Regulation Number	21 CFR 872.3820	21 CFR 872.3820	21 CFR 872.3820
Indications for use	Metapex Plus is a calcium hydroxide paste with iodoform, used as a temporary root canal filling material. Application : Root canal filling material/Apexification and hard tissue formation/Apexogensis.	Diapex Plus is a calcium hydroxide paste with iodoform, used as a temporary root canal filling material. Application : Root canal filling material/Apexification and hard tissue formation/Apexogensis.	For use to stimulate the healing process due to the mixture of calcium hydroxide and iodoform and the induction effect of these two ingredients. Used to promote healing effects and to help prevent bacterial contamination of the canal, as the two ingredients improved the induction effect for hard tissue induction and deposition. To be used as a medicament for the

			treatment of infected root canals, and as a permanent, low volume additive to the filling process of a treated root canal to assist in the induction and deposition of hard tissue to make the healing process more rapid and complete. For use in the treatment of infected root canals, or following pulpectomy, or for apexegenesis or apexification, and/or for the tip filling of prepared, treated root canals at the time of final filling with gutta-percha.
Raw Material	-Calcium hydroxide -Iodoform -Polydimethylsiloxane -Peppermint oil	-Calcium hydroxide -Iodoform -Polydimethylsiloxane -Olive oil	-Calcium hydroxide -Iodoform -Silicone Oil -Inert
Principle of Operation	Calcium-hydroxide based ointment material used to fill the root canal for a certain period of time Filled in a syringe for convenient implantation.	Calcium-hydroxide based ointment material used to fill the root canal for a certain period of time Filled in a syringe for convenient implantation.	Calcium-hydroxide based ointment material used to fill the root canal for a certain period of time Filled in a syringe for convenient implantation.
Performance Standard Conformance	Conformed to ISO 6876	Conformed to ISO 6876	Conformed to ISO 6876
Flowability	24mm	27.5mm	-
Radiopacity	5.4mm	2.8mm	-
Bio-compatibility	Yes	Yes	Yes
Sterility	Non-sterile	Non-sterile	Non-sterile
Shelf Life	2 years	3 years	3 years

Non-clinical Testing

The following testing was conducted on our subject device:

- Performance testing such as Appearance, Weight, Packaging according to Manufacturer standard.
- Performance testing of Flowability, Radio-opacity according to ISO 6876:2012.
- Biocompatibility Tests according to ISO 10993-1:2018, ISO 10993-2:2006, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2016, ISO 10993-10:2010, ISO 10993-11:2017, ISO 10993-12:2012
- 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.