September 29, 2023

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

Re: K232299
Trade/Device Name: CeraPutty
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: August 1, 2023
Received: August 1, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., CQIA
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: 06/30/2023
*See PRA Statement below.*

Submission Number *(if known)*

K232299

Device Name

CeraPutty

Indications for Use *(Describe)*

- Repair of Root Perforation
- Repair of Root Resorption
- Root End Filling
- Apexification
- Pulp Capping

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

**Submitter**
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**Device Information**

- Trade Name: CeraPutty
- Classification Name: resin, root canal filling
- Common Name: Root Canal Repair Filling Material
- Product Code: KIF
- Panel: Dental
- Regulation Number: 21 CFR 872.3820
- Device Class: Class II
- Date prepared: 09/06/2023

**Predicate Devices:**

- K092715, iRoot BP Plus by Innovative BioCeramix Inc.

**Device Description**

CeraPutty (Bioceramic Root Repair Material) is a ready-to-use, premixed bioceramic root repair material developed for permanent root canal repair and filling applications.
It is made of Calcium silicate composite, zirconium dioxide which is a radiopaque agent, and a thickening agent.
CeraPutty sets and hardens by the moisture inside the oral cavity. CeraPutty does not shrink during setting and demonstrates excellent physical properties.
CeraPutty does not require additional mixing for procedures, and its white color which allows aesthetic treatment.
Ceraputty is packaged in a preloaded syringe.

**Indication for Use**

- Repair of Root Perforation
- Repair of Root Resorption
- Root End Filling
- Apexification
- Pulp Capping

**Non-clinical Testing**
The following testing was conducted on our subject device:

- Biocompatibility Tests according to ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2016, ISO 10993-10:2010, ISO 10993-11:2017, and ISO 10993-23:2021
- Performance tests such as package and radio-opacity according to ISO 6876:2012
- Shelf Life test: ISO 6876 tests (setting time, Solubility)

**Summary of Technological Characteristics:**
The subject device and the predicate device have the same intended use and have similar technological characteristics and are made of similar 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.

The subject device is different from the predicate devices in raw materials, however, the test results provided in this submission support that it is substantially equivalent to the predicate device.

| | Subject Device | Predicate Device |
|---|---|---|
| Manufacturer | Meta Biomed Co., Ltd. | Innovative BioCeramix Inc. |
| Device Name | CeraPutty | iRoot BP Plus |
| 510(k) Number | K232299 | K092715 |
| Classification Name | resin, root canal filling | resin, root canal filling |
| Common Name | Root Canal Repair Filling Material | Root Canal Repair Filling Material |
| Product Code | KIF | KIF |
| Regulation Number | 21 CFR 872.3820 | 21 CFR 872.3820 |
| Indications for use | - Repair of Root Perforation<br>- Repair of Root Resorption<br>- Root End Filling<br>- Apexification<br>- Pulp Capping | - Repair of Root Perforation<br>- Repair of Root Resorption<br>- Root End Filling<br>- Apexification<br>- Pulp Capping |
| Raw Material | - Tricalcium silicate<br>- Zirconium dioxide<br>- Dicalcium silicate<br>- Tricalcium aluminate | - Tricalcium silicate<br>- Zirconium oxide<br>- Tantalum pentoxide<br>- Dicalcium silicate<br>- Calcium sulfate |
| Principle of Operation | CeraPutty Bioceramic Root Repair Material is a convenient ready-to-use white hydraulic premixed bioceramic material developed for permanent root canal repair and surgical applications. CeraPutty is an insoluble, radiopaque based on a calcium silicate composition, which requires the presence of water to set and harden. CeraPutty Bioceramic Root Repair Material does not shrink during | iRoot BP Plus Root Repair Material (iRoot BP Plus) is a convenient ready-to-use white hydraulic premixed bioceramic paste developed for permanent root canal repair and surgical applications. iRoot BP Plus is an insoluble, radiopaque and aluminum-free material based on a calcium silicate composition, which requires the presence of water to set and harden. |

| | | |
|---|---|---|
| | setting and demonstrates excellent physical properties.<br>CeraPutty is packaged in a preloaded container | iRoot BP does not shrink during setting and demonstrates excellent physical properties.<br>iRoot BP Plus is packaged in a preloaded container |
| Performance Standard | Conformed to ISO 6876 | Conformed to ISO 6876 |
| Setting time | 44 min | 5 h 10 min |
| Solubility | 0.1 % | 0.3% |
| Radio-opacity | 4.8 | 4.2 |
| Biocompatibility | Yes | Yes |
| Intended Operator | Dentist | Dentist |
| Sterility | Non-sterile | Non-sterile |
| Shelf Life | 2 years | 2 years |

**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.