February 14, 2023

Maruchi
Sungwook Jang
CEO
2-208, Medical Industry Complex Bldg., 42-10,
Taejanggongdan-gil
Wonju-si, Gangwon-do 26311
SOUTH KOREA

Re: K213757
Trade/Device Name: Endocem MTA Premixed Regular
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: May 20, 2022
Received: May 26, 2022

Dear Sungwook Jang:

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 -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213757

Device Name
ENDOCEM MTA PREMIXED REGULAR

Indications for Use *(Describe)*
The product is used for indirect pulp capping, direct pulp capping, root end filling and Repair of perforation.

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

Date: February 13, 2023

1. SUBMITTER

MARUCHI

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2. DEVICE

·Trade Name: ENDOCEM MTA PREMIXED REGULAR

·Common Name: Root Filling Material

·Classification Name: Resin, Root canal filling

·Regulation Number 872.3820

·Class: 2

·Classification Product Code: KIF

3. PREDICATE DEVICE

K082943, iRoot BP Injectable Root Canal Repair Filling Material, Innovative BioCeramix Inc

K102867, iRoot FS, Innovative BioCeramix Inc

4. DEVICE DESCRIPTION

ENDOCEM MTA PREMIXED REGULAR is a root canal filling material conforming to ISO 6876, in a pre-loaded syringe that does not require any pre-mixing and is set by absorbing moisture from the root canal environment.

5. INDICATIONS FOR USE

The product is used for indirect pulp capping, direct pulp capping, root end filling and

Repair of perforation.

6. PERFORMANCE TESTING (NON-CLINICAL)

The following test articles were tested based on the referenced standard. All the test results met the preset test criteria.

- Testing institution's method – Visual, Volume test, Setting time, pH
- ISO 6876 – Package, Extraneous matter, Setting time, Solubility, Radio-opacity
- ISO 10993-5 - Cytotoxicity (MTT)
- ISO 10993-10 - Guinea Pig Maximization Test for Skin sensitization (GPMT)
- ISO 10993-11 - Acute systemic toxicity
- ISO 10993-3 - Genotoxicity (Mammalian chromosome aberration test & Bacterial Reverse Mutation)

7. SUBSTANITAL EQUIVALENCE

	Proposed Device	**Predicate Device**	**Reference Device**	**Discuss/Justify the Differences**
510(k) Number	New	K082943	K102867	-
Trade Name	ENDOCEM MTA PREMIXED REGULAR	iRoot BP Injectable Root Canal Repair Filling Material	iRoot FS	-
Manufacturer	MARUCHI	Innovative BioCeramix Inc	Innovative BioCeramix Inc	-
Common Name	Root Filling Material	Root Filling Material	Root Filling Material	Equivalent
Classification Name	Resin, Root canal filling	Resin, Root canal filling	Resin, Root canal filling	Equivalent
Device Class	2	2	2	Equivalent

Product Code	KIF	KIF	KIF	Equivalent
Device Description	ENDOCEM MTA PREMIXED REGULAR is a root canal filling material conforming to ISO 6876, in a pre-loaded syringe that does not require any pre-mixing and is set by absorbing moisture from the root canal environment.	iRoot BP Injectable Root Canal Repair Filling Material (iRoot BP) is a convenient ready-to-use white hydraulic premixed injectable BioAggregate paste developed for permanent root canal repair and filling applications. iRoot BP is an insoluble, radiopaque and aluminum-free material based on a calcium silicate composition, which requires the presence of water to set and harden. iRoot BP does not shrink during setting and demonstrates excellent physical properties. iRoot BP is packaged in a preloaded syringe and is supplied with disposable tips.	iRoot FS Fast Set Root Repair Material (iRoot FS) is a convenient ready-to-use fast setting white hydraulic premixed bioceramic paste developed for permanent root canal repair of root perforation and root canal resorption, and root end filling, apexification and pulp capping applications. iRoot FS is an insoluble, radiopaque and aluminum-free material based on a calcium silicate composition, which requires the presence of water to set and harden. iRoot FS does not shrink during setting and demonstrates excellent physical properties. iRoot FS is available as a	

			preloaded syringe with disposable tips and a preloaded container.	
Indications for Use	The product is used for indirect pulp capping, direct pulp capping, root end filling and Repair of perforation.	· Repair of Root Perforation · Repair of Root Resorption · Root End Filling · Apexification · Pulp Capping	· Repair of Root Perforation · Repair of Root Resorption · Root End Filling · Apexification · Pulp Capping	Equivalent
Intended user	Dental professional	Dental professional	Dental professional	Equivalent
Standards	ISO 6876	ISO 6876	ISO 6876	Equivalent
Setting times	4.2 min	Minimum of 2 hours	Approximately 20 minutes	Differences
Chemical Composition	Zirconium dioxide Calcium silicate DMSO (Dimethylsulfoxide) Calcium aluminate Calcium sulfate Bentonite Hydroxypropyl Methyl Cellulose Silica Lithium carbonate Water Ethanol	Zirconium oxide Calcium silicates Tantalum pentoxide Calcium phosphate monobasic and filler agents.	Zirconium oxide Dicalcium silicate Tantalum pentoxide Tricalcium silicate Calcium Sulfate and filler agents	Differences

Liquid Formula	Paste type	Paste type	Paste type	Equivalent
Packaging	Pre-loaded syringe	Pre-loaded syringe	Pre-loaded syringe	Equivalent
Sterile	Non-sterile	Non-sterile	Non-sterile	Equivalent
Shelf Life	2 years	2 years	2 years	Equivalent

8. SUBSTANTIAL EQUIVALENCE DISCUSSION

ENDOCEM MTA PREMIXED REGULAR has the same Indications for Use and the principle of operations as the predicate device and reference device. It is intended purpose as they are placed into the root canal as a root filling materials which met the requirement according to ISO 6876. It has similar physical and biocompatible properties and demonstrates comparable performance specifications to the predicate devices.

The chemical compositions might slightly different from the predicate devices, both are used calcium silicate as base material, and additional components are used to improve flowability.

The bench and biocompatibility testing performed demonstrates that any differences in their technological characteristics do not raise any new questions as to safety and effectiveness. Therefore, it is concluded that ENDOCEM MTA PREMIXED REGULAR is substantially equivalent to the predicate devices. Hence, its equivalent is acceptable.