March 24, 2021

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

Re: K202015
Trade/Device Name: White ENDOSEAL MTA
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: January 15, 2021
Received: January 27, 2021

Dear Sung 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, 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

4. INDICATION FOR USE STATEMENT

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)*
K202015

Device Name
White ENDOSEAL MTA

Indications for Use *(Describe)*
Permanent root canal obturation

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date: August 20, 2020

1. SUBMITTER

MARUCHI

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Email: ra@endocem.com

2. DEVICE

·Trade Name: White ENDOSEAL MTA

·Common Name: Root Filling Material

·Classification Name: Resin, Root canal filling

·Regulation Number 872.3820

·Class: 2

·Classification Product Code: KIF

3. PREDICATE DEVICE

K170175, ENDOSEAL MTA, MARUCHI

4. DEVICE DESCRIPTION

This product is the root canal sealer conforming to ISO 6876. This is a pre-loaded syringe type that does not require mixing and set by absorbing the moisture around the root canal.

5. INDICATIONS FOR USE

Permanent root canal obturation

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 - Capacity, pH
- ISO 6876 – Package, Extraneous matter, Flow, Setting time, Film Thickness, 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**	**Discuss/Justify the Differences**
510(k) Number	K202015	K170175	-
Trade Name	White ENDOSEAL MTA	ENDOSEAL MTA	-
Manufacturer	MARUCHI	MARUCHI	-
Common Name	Root Filling Material	Root Filling Material	Equivalent
Classification Name	Resin, Root canal filling	Resin, Root canal filling	Equivalent
Device Class	2	2	Equivalent
Product Code	KIF	KIF	Equivalent
Device Description	This product is the root canal sealer conforming to ISO 6876. This is a pre-loaded syringe type that does not require mixing and set by absorbing the	ENDOSEAL MTA is an endodontic sealer based on MTA, providing a root canal filling. It is premixed and pre-loaded in a syringe, which allows a complete	Equivalent

	moisture around the root canal.	filling of the entire root canal including accessory and lateral canals.	
Indications for Use	Permanent root canal obturation	* Permanent obturation of the root canal following vital pulp-extirpation * Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.	Equivalent
Intended user	Dental professional	Dental professional	Equivalent
Standards	ISO 6876	ISO 6876	Equivalent
Physical properties	Setting time: 29 min Flow: 22 mm Radiopacity: 7.7 mm Flim thickness: 14 μm Solubility: 0.3 %	Setting time: 12.31 min Flow: 21 mm Radiopacity: 10.14 mm Flim thickness: 15 μm Solubility: 0.7 %	Differences
Chemical Composition	-Zirconium dioxide -Dimethyl sulfoxide -Calcium silicate (Tricalcium silicate) -Water -Bentonite Clay -Polyvinyl alcohol -Polyvinyl pyrrolidone -Lithium Carbonate	-Natural Pure Cement -Zirconium dioxide -Bismuth trioxide - Bentonite Clay -n-Methyl-2-Pyrrolidone -Hypromellose	Differences
Liquid Formula	Paste type	Paste type	Equivalent
Packaging	Pre-loaded syringe	Pre-loaded syringe	Equivalent

Sterile	Non-sterile	Non-sterile	Equivalent
Shelf Life	2 years	2 years	Equivalent

8. SUBSTANTIAL EQUIVALENCE DISCUSSION

White ENDOSEAL MTA has the same Indications for Use and the principle of operations as the predicate devices. 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 White ENDOSEAL MTA is substantially equivalent to the predicate devices. Hence, its equivalent is acceptable.