Maruchi
Priscilla Chung
Regulatory Affairs Consultant
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800 Roosevelt STE 417
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February 26, 2018

Re: K170175
Trade/Device Name: Endoseal MTA
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: January 17, 2018
Received: January 26, 2018

Dear Priscilla Chung:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170175

Device Name

ENDOSEAL MTA

Indications for Use *(Describe)*

- 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.

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

(K170175)

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: ___01/17/2018___

1. Applicant / Submitter:

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2. Submission Correspondent:

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3. Device:

Proprietary Name:	ENDOSEAL MTA
Common Name:	Root Filling Material
Classification Name:	Root Canal Filling Resin
Classification:	Class II, 21 CFR 872.3820
Classification Product Code:	KIF

4. Predicate Device:

ENDOSEAL (K133054) by MARUCHI
MTA Fillapex (K113568) by Angelus Industria de Produtos Odontologicos
IROOT SP (K080917) by Innovative BioCeramix Inc.

5. Device Description:

ENDOSEAL MTA is an endodontic sealer based on MTA, providing a biocompatible and effective root canal filling. It is premixed and pre-loaded in a syringe, which allows a complete filling of the entire root canal including accessory and lateral canals. The product is eugenol-free and will not impede adhesion inside the root canal.

6. Indications for Use

- 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.

7. Performance Data(Non-Clinical):

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

- ISO 6876 – Visual, Capacity, Packaging, Flow, Setting time, Film Thickness, Solubility and Radiopacity
- Shelf Life Test - ISO 6876 (Visual, Packaging, Setting time, Solubility)
- ISO 10993-5 - Cytotoxicity
- ISO 10993-10 - Maximization test for delayed hypersensitivity (LLNA)
- ISO 10993-11 - Acute systemic toxicity
- ISO 10993-6 - Implantation
- ISO 10993-3 - AMES & Mammalian Erythrocyte Micronucleus

8. Substantial Equivalence

	Proposed Device (K170175)	Predicate Device (K133054)	Predicate Device (K113568)	Predicate Device (K080917)	Discuss/Justify the Differences
Trade Name	ENDOSEAL MTA	ENDOSEAL	MTA Fillapex	IROOT SP	
Device Description	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 filling of the entire root canal including accessory and lateral canals.	The raw materials of the ENDOSEAL are Natural Pure Cement, Zirconium dioxide, and Citric acid anhydrous. It is prepared as a mixture of powder and water, and it is used in a putty form which gradually hardens in the oral environment.	MTA Fillapex is a mineral trioxide aggregate(MTA) and resin root canal sealer used during endodontic treatment to permanently fill the canal system following debridement and disinfection. It consists of two component pastes that are combined in a dual barrel syringe for ease of dispensing and consistent dosage.	iRoot SP Root Canal Sealer(IRoot SP) is premixed ready-to-use injectable white hydraulic cement paste developed for permanent root canal filling and sealing applications. iRoot SP 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 SP is packaged in a pre-loaded syringe and is supplied with disposable Intra Canal Tips.	Equivalent
Common Name	Root Filling Material	Root Filling Material	Root Filling Material	Root Filling Material	Equivalent
Classification Name	Root Canal Filling Resin	Root Canal Filling Resin	Root Canal Filling Resin	Root Canal Filling Resin	Equivalent
Class	Class II	Class II	Class II	Class II	Equivalent
Product Code	KIF	KIF	KIF	KIF	Equivalent
Indications for Use	▪ Permanent obturation of the root	▪ Repair of perforation ▪ Root canal filling	MTA Fillapex is a root canal sealer	▪ Permanent obturation of the root	Equivalent

	canal following vital pulp-extirpation ▪ Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.		intended for the permanent sealing of root canals and may be used in combination with root canal obturation materials.	canal following vital pulp-extirpation ▪ Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings. iRoot SP is suitable for use in the single cone and lateral condensation technique.	
Shelf Life	2 years	2 years	2 years	-	Equivalent
Standards	ISO 6876	ISO 6876	ISO 6876	ISO 6876	Equivalent
Basic Chemical Composition	Natural pure cement Zirconium dioxide Bismuth trioxide Bentonite Clay n-Methyl-2-Pyrrolidone Hypromellose	Natural pure cement Zirconium dioxide Citric acid anhydrous	Dicalcium and tricalcium silicate, tricalcium aluminate, calcium oxide, pentaerythritol rosinate, n-ethyl-o, p-toluenesulfonamide salicylate resin, bismuth oxide, fumed silica, titanium dioxide	Zirconium oxide Calcium silicates Calcium phosphate monobasic Calcium hydroxide Filler and thickening agents	The main ingredients are similar but some other ingredients are different. However, the biocompatibility and the performance test results supported that the subject device is substantially equivalent to the predicate devices.
Liquid Formula	Premixed type	Mixing with distilled water	Mixing through a dual barrel syringe	Premixed type	Equivalent
Packaging	Pre-loaded syringe	Vial	Dual barrel syringe	Pre-loaded syringe	Equivalent
Sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Equivalent

ENDOSEAL MTA has the same indications for use and the principle of operations as the predicate devices. It has similar physical and biocompatible properties, and demonstrates comparable performance specifications to the predicate devices. In addition, ENDOSEAL MTA has a comparable delivery system to IROOT SP.

Endoseal MTA and all of the predicate devices are equivalent as they all release calcium silicate oxide and calcium hydroxide by undergoing setting reactions when water reacts with calcium oxide. The reaction results in near identical composition of products after setting, as all of liquid components would have expelled during the setting reaction. Hence, all of the products resulted in similar test results including the cytotoxicity test.
The material compositions might slightly different from the predicate devices, however, despite of this difference, the test results of biocompatibility and performance tests show that the subject device is substantially equivalent to the predicate devices.

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 ENDOSEAL MTA is substantially equivalent to the predicate devices.

9. Conclusion:

Based on the testing results, MARUCHI concludes that the ENDOSEAL MTA is substantially equivalent to the predicate devices.