October 3, 2024

Longly Biotechnology (wuhan) CO., LTD
℅ Alice Wu
RA Manager
Wuhan Tacro Technology Co., Ltd.
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East Lake High-tech Development Zone
Wuhan, Hubei 430070
CHINA

Re: K241977
Trade/Device Name: Injectable Root Canal Bioceramic Sealer (i-MTA SP)
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: May 10, 2024
Received: July 5, 2024

Dear Alice Wu:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241977

Device Name

Injectable Root Canal Bioceramic Sealer (i-MTA SP)

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.
i-MTA SP Injectable Root Canal Bioceramic Sealer is suitable for use in the single cone 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 K241977

"510(k) Summary" as required by 21 CFR Part 807.92.

Date: 2024-10-03

I. Submitter

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III. Device

Type of 510(k): Traditional

Common Name: Injectable Root Canal Bioceramic Sealer

Trade Name: Injectable Root Canal Bioceramic Sealer

Model: i-MTA SP

Regulation Name: Root Canal Filling Resin

Regulation Number: 21 CFR 872.3820

Regulation Name: Root Canal Filling Resin

Review Panel: General & Plastic Surgery

Regulatory Class: II

Product Code: KIF- Resin, Root Canal Filling

IV. Predicate Device

Device	**Primary predicate device**	**Reference device**
510 k number	K212983	K080917
Trade Name	Injectable Root Canal Bioceramic Sealer	iRoot SP Root Canal Sealer
Model	C-Root SP	iRoot SP
Manufacturer	Beijing C-Root Dental Medical Devices Co., LTD.	Innovative BioCeramix Incorporated
Classification	II	II
Regulation Number	21 CFR 872.3820	21 CFR 872.3820
Product Code	KIF	KIF

V. Device Description

i-MTA SP Injectable Root Canal Bioceramic Sealer is a convenient premixed ready-to-use, injectable white hydraulic bioceramic paste developed for permanent root canal filling and sealing applications. an injectable mineral trioxide aggregate. i-MTA SP is used for root canal sealing and permanent obturation. It is an insoluble and radiopaque material based on a calcium silicates composition, which requires the presence of water to set and harden. i-MTA SP is packaged in an

oral irrigator and is supplied with disposable Intra Canal Tips. i-MTA SP may be delivered into the canal via the disposable tips or it can be delivered via traditional methods.

VI. 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.

i-MTA SP Injectable Root Canal Bioceramic Sealer is suitable for use in the single cone and placement of intracanal dressings.

VII.Comparison of Technological Characteristics With the Predicate Device

i-MTA SP Injectable Root Canal Bioceramic Sealer raises no safety or efficacy concerns when compared to the predicate devices.

A technical comparison to the predicate is provided below:

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference device**
K Number	Applying K241977	K212983	K080917
Trade name	Injectable Root Canal Bioceramic Sealer	Injectable Root Canal Bioceramic Sealer	iRoot SP Root Canal Sealer
Model	i-MTA SP	C-Root SP	iRoot SP
Classification name	Root Canal Filling Resin	Root Canal Filling Resin	Root Canal Filling Resin
Product code	KIF	KIF	KIF
Intended use/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	• Permanent obturation of the root canal following vital pulp-extirpation • Permanent obturation of the root canal following removal of infected or necrotic pulp and	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

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference device**
	placement of intracanal dressings. i-MTA SP Injectable Root Canal Bioceramic Sealer is suitable for use in the single cone and placement of intracanal dressings.	placement of intracanal dressings. C-Root SP Injectable Root Canal Bioceramic Sealer is suitable for use in the single cone and lateral condensation technique.	intracanal dressings. iRoot SP is suitable for use in the single cone and lateral condensation technique.
Targeted anatomic site	Root canal following vital pulp-extirpation	Root canal following vital pulp-extirpation	Root canal following vital pulp-extirpation
Targeted population	Human tooth root canal	Human tooth root canal	Human tooth root canal
Prescription Use	Yes	Yes	Yes
Basic Chemical Composition	**Zirconium Oxide,** **Calcium Silicates,** **Calcium Phosphates,** **Calcium Hydroxide,** Polyethylene glycol, Hydroxypropyl methyl cellulose	**Zirconium Oxide,** Strontium Silicates, **Calcium Phosphates,** **Calcium Hydroxide,** Tantalum Oxide and Filler Agents.	**Zirconium oxide,** **Calcium silicate,** **Calcium hydroxide,** **Calcium phosphate,** Monobasic and Filler Agents
Performance Standard Conformance	Conformed to ISO 6876 and Technical Requirements., adding Appearance, Size change after curing.	Conformed to ISO 6876. and conformed to Technical Requirements of "Injectable Root Canal Bioceramic Sealer" adding	Conformed to ISO 6876.

Comparison Elements	Subject Device	Predicate Device	Reference device
		Appearance, Dimensional change following setting, pH.	
Duration of Contact	Permanent contact - contact exceeds 30d	Permanent contact - contact exceeds 30d	Permanent contact - contact exceeds 30d
Biocompatibility	Biocompatibility Assessment per FDA Biocompatibility Guidance Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.	Comply with ISO 10993-1:2018, FDA Guidance, tests included cytotoxicity, irritation, sensitization, acute systemic toxicity, subchronic systemic toxicity test, implantation effect, endodontic usage test, Ames test and TK test.	Biocompatibility Assessment per FDA Biocompatibility Guidance Use of International Standard ISO 10993-1

VIII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

- ISO 6876:2012 Dentistry - Root canal sealing materials.

-Endodontic usage Test- ISO 7405:2018 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

-Biocompatibility Assessment per FDA Biocompatibility Guidance Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Summary

Injectable Root Canal Bioceramic Sealer 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.

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VIII. Conclusions

Injectable Root Canal Bioceramic Sealer 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 material which met the requirement according to ISO 6876. It has similar physical and biocompatible properties and demonstrates comparable performance specifications to the predicate equivalent is acceptable.

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 i-MTA SP is substantially equivalent to the predicate devices. Hence, its equivalent is acceptable.