December 12, 2024

Longly Biotechnology (Wuhan) Co., Ltd.
℅ Shirely Kong
RA
Beijing Xinranyicheng Medicine & Technology Co., Ltd.
A-15B01, Langqin International Building, No.168,
Guang'anmen Outer Street, Xicheng District
Beijing, Beijing 100053
China

Re: K242934
Trade/Device Name: Bioceramic Root Canal Sealer and Repair Materials (i-MTA BP)
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF,
Dated: September 14, 2024
Received: September 25, 2024

Dear Shirely Kong:

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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, MChE, RAC, 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.

510(k) Number *(if known)*
K242934

Device Name
Bioceramic Root Canal Sealer and Repair Materials

Indications for Use *(Describe)*

i-MTA BP Bioceramic Root Canal Sealer and Repair Material is developed for permanent root canal sealer and repair and surgical applications.
- 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.

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

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510(k) Summary K242934

This summary of 510(k) substantial equivalence is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

Name: Longly Biotechnology (wuhan) Co., Ltd
Address: No.02 of 2nd Floor, Building A2-2, Optics Valley Biomedical Park, Gaoxin Avenue No.858, East Lake High-tech Development Zone, Wuhan, China
Tel: +86 - 13907166169
Contact: Yan Liang (Registration manager)
Email: longlyyanliang466@163.com
Date of Preparation: Sep.8,2024

2.0 Device Information

Trade Name: Bioceramic Root Canal Sealer and Repair Materials
Model: i-MTA BP
Common Name: Root canal filling resin
Classification Name: Resin, Root Canal Filling
Device Panel: Dental
Classification Regulation: 21 CFR 872.3820
Device Classification: Class II
Product Code: KIF

3.0 Identification of Predicate Device and Reference Device

Information	Predicate Device	Reference Device
510(k) Number	K240365	K092715
Device Name	Bioceramic Root Repair Material (C-Root BP)	IROOT BP PLUS
Common Name	Bioceramic Root Repair Material	Root Repair Material
Classification Name	Resin, Root Canal Filling	Resin, Root Canal Filling
Device Panel	Dental	Dental
Classification Regulation	21 CFR 872.3820	21 CFR 872.3820
Device Classification	Class II	Class II
Product Code	KIF	KIF
Manufacturer	Beijing C-Root Dental Medical Devices Co., LTD.	Innovative BioCeramix, Inc.

4.0 Device Description

i-MTA BP Bioceramic Root Canal Sealer and Repair Materials is a ready-to-use premixed bioceramic paste developed for permanent root canal sealer and repair and surgical applications. i-MTA 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. i-MTA BP does not shrink during setting and demonstrates excellent physical properties. i-MTA BP is packaged in a preloaded syringe.

5.0 Indication for Use

i-MTA BP Bioceramic Root Canal Sealer and Repair Material is developed for permanent root canal sealer and repair and surgical applications.

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

6.0 Comparison of Product Properties with the Predicate Device

The subject device Bioceramic Root Canal Sealer and Repair Materials(i-MTA BP) met all design specifications as was Substantially Equivalent (SE) to the predicated device.

<table>
<tr><th>Comparison Items</th><th>Subject Device</th><th>Predicate Device</th><th>Reference Device</th><th>Comparison</th></tr>
<tr><td>K Number</td><td>K242934</td><td>K240365</td><td>K092715</td><td>--</td></tr>
<tr><td>Trade name</td><td>Bioceramic Root Canal Sealer and Repair Materials</td><td>Bioceramic Root Repair Material</td><td>IROOT BP PLUS</td><td>--</td></tr>
<tr><td>Model</td><td>i-MTA BP</td><td>C-Root BP</td><td>iRoot BP Plus</td><td>--</td></tr>
<tr><td>Classification name</td><td>Resin, Root Canal Filling</td><td>Resin, Root Canal Filling</td><td>Resin, Root Canal Filling</td><td>Same</td></tr>
<tr><td>Product code</td><td>KIF</td><td>KIF</td><td>KIF</td><td>Same</td></tr>
<tr><td>Class</td><td>II</td><td>II</td><td>II</td><td>Same</td></tr>
<tr><td>Intended use/Indications for Use</td><td>• Root End Filling
• Repair of Root Perforation
• Repair of Root Resorption
• Apexification
• Pulp Capping</td><td>• Repair of Root Perforation
• Repair of Root Resorption
• Root End Filling
• Apexification
• Pulp Capping</td><td>• Repair of Root Perforation
• Repair of Root Resorption
• Root End Filling
• Apexification
• Pulp Capping</td><td>Same</td></tr>
<tr><td>Targeted Site</td><td>Root canal</td><td>Root canal</td><td>Root canal</td><td>Same</td></tr>
<tr><td>Prescription Use</td><td>Yes</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>Chemical Composition</td><td>Calcium silicate, zirconium oxide, tantalum pentoxide, calcium sulfate and filler agents.</td><td>Zirconium oxide, strontium silicate, calcium phosphates, calcium hydroxide, tantalum oxide and filler agents.</td><td>Tricalcium silicate, dicalcium silicate, zirconium oxide, tantalum pentoxide, calcium sulfate and filler agents.</td><td>Analysis 1</td></tr>
<tr><td>Performance Standard Conformance</td><td>
<table>
<tr><th>Standards or other guidelines/ referential used</th><th>Performances</th></tr>
<tr><td>ISO 6876:2012</td><td>Setting time</td></tr>
<tr><td>ISO 6876:2012</td><td>Solubility</td></tr>
<tr><td>ISO 6876:2012</td><td>Radio-opacity</td></tr>
<tr><td>Technical Specifications</td><td>Composition</td></tr>
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<tr><td>Technical Requirements</td><td>Appearance</td></tr>
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<tr><td>ISO 6876:2012</td><td>Radio-opacity</td></tr>
<tr><td>Technical Requirements</td><td>Appearance</td></tr>
</table>
</td><td>Same as predicated device</td></tr>
</table>

Comparison Items	**Subject Device**	**Predicate Device**	**Reference Device**	**Comparison**
	Technical Specifications: Content Technical Specifications=ISO6876:2001: Size change after curing Technical Specifications: pH Technical Specifications: Acid-soluble arsenic and lead contents Technical Specifications: Heavy metal	Technical Requirements: Dimension changes after setting Technical Requirements: pH	Technical Requirements: Dimension changes after setting Technical Requirements: pH	
Duration of Contact	Permanent contact - contact exceeds 30d	Permanent contact - contact exceeds 30d	Permanent contact - contact exceeds 30d	Same
Biocompatibility	Comply with ISO 10993-1, ISO 7405 and FDA Guidance	Comply with ISO 10993-1, ISO 7405 and FDA Guidance	Comply with ISO 10993-1, ISO 7405 and FDA Guidance	Same

Analysis

1. The subject device Bioceramic Root Canal Sealer and Repair Materials(i-MTA BP) has the same intended use and comparable materials as the predicated device C-Root BP (K240365).
2. The chemical composition of the subject device Bioceramic Root Canal Sealer and Repair Materials is different with the predicated device C-Root BP (K240365).
   The subject device uses calcium silicates whereas the predicated device uses strontium silicate. Calcium silicates and strontium silicates are all belong to silicate. The subject device uses calcium sulfate whereas the predicated device uses calcium phosphates and calcium hydroxide. They are all belong to calcium salt. They all can be set and harden upon the moisture in the dentin. They all play the same role in each's formula. Also, Calcium silicates have better biocompatibility.
   The subject device Bioceramic Root Canal Sealer and Repair Materials(i-MTA BP) has the same formulation/ processing/ non-sterilization/ principal of setting/ final form after setting as the reference device iRoot BP Plus (K092715), and no other chemical composition has been added.
   All the raw materials of the subject device are all used in the reference device (K092715). Biocompatibility testing of the subject device and the reference device (K092715) performed meet ISO 10993 biocompatibility and FDA guidance requirements.
3. Also, the performance comparison testing including composition/appearance, setting time, size changes after curing, solubility, radiopacity, pH of 'Bioceramic Root Canal Sealer and Repair Materials' and C-Root BP provide the evidence that chemical and physical properties are substantially equivalent.

7.0 Summary of Testing

Performance Testing – Bench

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use. The following tests were performed on the device.

Standards or other guidelines/ referential used	**Performances**	**Requirements**	**Compliance result**
ISO 6876:2012	Setting time	2h-6h	2.5h
ISO 6876:2012	Solubility	< 3%	2.80%
ISO 6876:2012	Radio-opacity	> 3mm Al	> 3mm Al
Technical Specifications	Composition	The product composition should not contain any visible foreign objects to the naked eye.	Compliant with requirements
Technical Specifications	Content	Not less than 93% of the indicated loading capacity.	Compliant with requirements
Technical Specifications=ISO6876:2001	Size change after curing	< 1.0%	-0.50%
Technical Specifications	pH	11.5-13.5	12.29
Technical Specifications	Acid-soluble arsenic and lead contents	The maximum content of acid-soluble arsenic is 2mg/kg, the maximum content of acid-soluble	Compliant with requirements

		lead is 100mg/kg	
Technical Specifications	Heavy metal	< 100 μg/g	< 100 μg/g

Clinical testing was not required for this submission.

Biocompatibility Testing

Biocompatibility testing was performed in accordance with the ISO 10993-1, ISO 7405 and FDA guidance document Use of International Standard ISO 10993-1, “Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process.”

Testing included the following:

• Cytotoxicity (ISO 7405:2018)
• Sensitization (ISO 10993-10:2021)
• Irritation (ISO 10993-10:2021)
• Acute Systemic Toxicity (ISO 10993-11: 2017)
• TK Gene Mutation Test (ISO 10993-3:2014)
• Bacterial Reverse Mutation Test (ISO 10993-3:2014)
• Subchronic Systemic Toxicity (ISO 10993-11: 2017)
• Implantation (ISO10993-6:2016)
• Pulp Capping Testing (ISO7405:2018)
• Endodontic Usage Test (ISO 7405:2018)

All the results of biocompatibility testing demonstrate that the subject devices are complied with the biocompatibility requirements.

Summary

Bioceramic Root Canal Sealer and Repair Materials 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 devices.

8.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the differences between the subject device and the predicated device C-Root BP are insignificant in terms of substantial equivalence. The subject device is substantially equivalent to the predicate device C-Root BP.