May 10, 2024

Beijing C-Root Dental Medical Devices Co., Ltd.
Bingmin Wu
Official Correspondent
Room 301, Building 10, Yard 12
Middle Juyuan Road, Mapo Town, Shunyi
Beijing, 101300
China

Re: K240365
Trade/Device Name: Bioceramic Root Repair Material (C-Root BP)
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: November 25, 2023
Received: February 6, 2024

Dear Boyle Wang:

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.

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, M.ChE., 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240365

Device Name

Bioceramic Root Repair Material (C-Root BP)

Indications for Use *(Describe)*

•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.

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510(k) Summary

K240365

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: Beijing C-Root Dental Medical Devices Co., LTD.

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Fax: +86- 10-51727496

Contact: Bingmin Wu

Date of Preparation: Apr.23,2024

2.0 Device Information

Trade name: C-Root BP

Common name : Bioceramic Root Repair Material

Classification name: Resin, Root Canal Filling

Model: C-Root BP

Production code:KIF

Regulation number:21 CFR 872.3820

Classification:Class II

Panel:Dental

Manufacturer: Beijing C-Root Dental Medical Devices Co., LTD.

3.0 Identification of Predicated Device and Reference device

Primary Predicate Device:

510(k) Number: K092715

510(k) Summary

Product Name: iRoot BP Plus

Common Name:Bioceramic Root Repair Material

Production code:KIF

Regulation number:21 CFR 872.3820

Classification:Class II

Panel:Dental

Manufacturer: Innovative BioCeramix, Inc.

Reference device:

510(k) Number: **K212983**

Product Name: Injectable Root Canal Bioceramic Sealer

Common Name:Root Canal Sealer

Model: C-Root SP

Production code:KIF

Regulation number:21 CFR 872.3820

Classification:Class II

Panel:Dental

Manufacturer:Beijing C-Root Dental Medical Devices Co., LTD.

4.0 Indication for Use Statement

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

5.0 Device Description

C-Root BP Bioceramic Root Repair Material (C-Root BP) is a convenient ready-to-use premixed bioceramic paste developed for permanent root canal repair and surgical

applications. C-Root BP is an insoluble, radiopaque and aluminum-free material based on a strontium silicate composition, which requires the presence of water to set and harden. C-Root BP does not shrink during setting and demonstrates excellent physical properties. C-Root BP is packaged in a Preloaded syringe.

6.0 Summary of Non-Clinical Testing

Non clinical tests were conducted to verify that the subject device C-Root BP met all design specifications as was Substantially Equivalent (SE) to the predicated device.

Mechanical Performance Comparison Testing:

The following test data was gathered according to the ISO 6876:2012 testing for the subject and predicated devices: see summary table 1 below:

Table 1 Summary of non-clinical performance testing according to the ISO 6876:2012

Test	Criteria	Subject Device C-Root BP	Predicated Device iRoot BP Plus
Setting time	When determined in accordance with 3.3, the setting time of the sealing material measured shall not exceed 72 h.	2h	17h
Solubility	When determined in accordance with 3.6, the solubility of setting sealing Measured shall not exceed 3.0 % by mass. The specimen shall show no evidence of disintegration when examined visually.	1.4%	1.71%

Radio-opacity	When determined in accordance with 3.7,the sealing material shall have a radio-opacity equivalent to not less than 3mm of aluminium	Meets requirement	Meets requirement

As defined in the testing data from the Subject and predicated device the ISO 6876:2012 was used and followed for most parts.

Some of the testing recommended by the standard ISO 6876:2012, such as the flow/working time/ film thickness are not suitable for the subject device and predicate device.Because the intend use such as repair and root end filling need putty stable and can not flow.

In addition, Additional tests including Appearance，Dimension changes after setting and pH were performed per the Technical Requirements of “Bioceramic Root Repair Material” provided by our company.

Table 2 Summary of non-clinical performance testing according to the Technical Requirements of “Bioceramic Root Repair Material” provided by our company

Test	Criteria	Subject Device C-Root BP	Predicated Device iRoot BP Plus
Appearance	The sealer material is milky white paste, and shall be visually free from extraneous matter when examined under normal visual acuity.	Meets requirement	Meets requirement
Dimension changes after setting	Measured mean dimensional change in length of this sealer shall not exceed 1.0% in shrinkage or 0.1% in expansion.	-0.44%	-0.48%
pH	The pH of the sealer material should be greater than 11.	12.68	12.27

All the non clinical tests results verify that the subject device C-Root BP and the predicated

device meet the product acceptance criteria.

Biocompatibility:

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 10993-5:2009)
- Sensitization (ISO 10993-10:2021)
- Intracutaneous Irritation (ISO 10993-23:2021)
- Acute Systemic Toxicity(ISO 10993-11: 2017)
- Subchronic Systemic Toxicity (ISO 10993-11: 2017)
- Bacterial Reverse Mutation Test(ISO 10993-3:2014)
- Mammalian Cell Gene Mutation Test(ISO 10993-3:2014)
- Pulp Capping Testing(ISO7405:2008)
- Implantation Tests(ISO10993-6:2016)

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

Since the chemical composition of the subject device C-Root BP is based on principal chemical components in C-Root SP(K212983), the biocompatibility test data of C-Root SP provide further evidence of biocompatibility and over all safety for C-Root BP,

7.0 Summary of Clinical Testing

Clinical testing was not required for this submission.

8.0 Technological Characteristics and Substantial Equivalence

The following table shows similarities and differences of use, design, and material between the subject device and the predicated devices.

Table 3 General Device Characteristics Comparison

Item	Subject device K240365	Predicated device K092715	Reference device K212983	Remark
Product name	C-Root BP	iRoot BP Plus	Injectable Root Canal Bioceramic Sealer	--
510K Number	K240365	K092715	K212983	
Product Code	KIF	KIF	KIF	Same
Regulation No.	21 CFR 872.3820	21 CFR 872.3820	21 CFR 872.3820	Same
Class	II	II	II	Same
Intended Use	•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	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.	Same as Predicate device
Prescription Use	Yes	Yes	Yes	Same
Basic Chemical Composition	Zirconium Oxide, Strontium Silicate, Calcium Phosphates	calcium silicates, Zirconium oxide, tantalum pentoxide,	Zirconium Oxide, Strontium Silicate, Calcium Phosphates,	Analysis 1

	Calcium Hydroxide, Tantalum Oxide and filler agents.	Calcium sulfate(anhydrous) calcium phosphate monobasic, filler agents	Calcium Hydroxide, Tantalum Oxide and filler agents.	
Performance Standard Conformance	Appearance, Setting time, Dimensional change following setting, Solubility, Radio-opacity, pH, Microorganism	Appearance, Setting time, Dimensional change following setting, solubility, Radio-opacity and pH	Appearance,Flow, Film thickness, setting time, dimensional change following setting, solubility, Radio-opacity, pH , Microorganism	Same as Predicated device
Treatment Site	Root canal	Root canal	Root canal	Same
Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Biocompatibility	Comply with ISO 10993-1 and FDA guidance	Comply with ISO 10993-1:2018 FDA guidance	Comply with ISO 10993-1:2018 FDA guidance	Same
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Same

Analysis:

1.The subject device C-Root BP has the same intended use and comparable materials as the predicated device iRoot BP Plus (K092715).

2. Chemical composition of the subject device C-Root BP is different with that of the predicated device. The subject device uses strontium silicate whereas the predicated device uses calcium silicates. Strontium silicate and calcium silicates are all belong to silicate and

can be set and harden upon the moisture in the dentin. Also, strontium silicate has better radiation resistance than calcium silicates.

The subject device C-Root BP has the same formulation component / processing / non-sterilization /principal of setting / final form after setting as the Reference device C-Root SP (K212983), and no other chemical filler agent has been added.

All the raw materials of the subject device C-Root BP including strontium silicate are all used in the reference device (K212983). Biocompatibility testing of the subject device C-Root BP and the reference device (K212983) performed meet ISO 10993 biocompatibility and FDA guidance requirements.

3. Also, the performance comparison testing including appearance, setting time, dimension changes after setting, solubility, radiopacity, pH of C-Root BP and iRoot BP Plus provide the evidence that chemical and physical properties are substantially equivalent.

9.0 Conclusion

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