December 8, 2021

Beijing C-Root Dental Medical Devices Co., LTD.
Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801 ,No.161, East Lu Jiazui Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K212983
Trade/Device Name: Injectable Root Canal Bioceramic Sealer
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: November 26, 2021
Received: December 6, 2021

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 (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,

For Michael E. Adjodha, M.ChE.
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)*

K212983

Device Name
Injectable Root Canal Bioceramic Sealer

Indications for Use *(Describe)*

* Permanent obturation of the root canal following vital pulpextirpation.
* Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.

C-Root SP Injectable Root Canal Bioceramic Sealer is suitable for use in the single cone and lateral condensation technique.

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.

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K212983
510(k) Summary

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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Contact: Bingmin Wu
Date of Preparation: Aug.25,2021

Designated Submission Correspondent

Mr. Boyle Wang
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Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device Information

Trade name: Injectable Root Canal Bioceramic Sealer
Common name: Root Canal Sealer
Classification name: Resin, Root Canal Filling
Model: C-Root SP

3.0 Classification

Production code: KIF
Regulation number: 21 CFR 872.3820
Classification: Class II
Panel: Dental

4.0 Identification of Predicate Device and Reference Device

Predicate Device:

510(k) Number: K080917
Product Name: iRoot SP

Manufacturer: Innovative BioCeramix, Inc.

5.0 Indication for Use Statement

● 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.

C-Root SP Injectable Root Canal Bioceramic Sealer is suitable for use in the single cone and lateral condensation technique.

6.0 Device Description

C-Root 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. C-Root SP is an insoluble, radiopaque and aluminum-free material based on a strontium silicates composition, which requires the presence of water to set and harden. C-Root SP does not shrink during setting and demonstrates excellent physical properties. C-Root SP is packaged in a preloaded syringe and is supplied with disposable Intra Canal tips. C-Root SP may be delivered into the canal via the disposable tips or it can be delivered via traditional methods.

C-Root SP Injectable Root Canal Bioceramic Sealer is available in three preloaded syringe mode that provide different in specification in2g;

1g; 0.5g. The only difference between the types are the net weight.

7.0 Summary of Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 6876:2012 Dentistry - Root canal sealing materials.

Biocompatibility testing

- Ames Test - ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
-Mouse Lymphoma Cells(TK) Gene Mutation Test- ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- In Vitro Cytotoxicity Test - ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Sensitization - ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Intracutaneous Reactivity Test - ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Acute systemic Toxicity Test - ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Subchronic systemic Toxicity Test - ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Bone Implantation effects - ISO 10993-6:2016 Biological evaluation of the medical devices – Part 6: Tests for Local Effects after Implantation.
-Endodontic usage Test- ISO 7405:2018 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

8.0 Summary of Clinical Testing

Clinical testing was not required for this submission.

9.0 Technological Characteristics and Substantial Equivalence

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

Table 1 General Device Characteristics Comparison Table

Item	Subject device	Predicate device K080917	Remark
Product Name	Injectable Root Canal Bioceramic Sealer	iRoot SP	--
Product Code	KIF	KIF	Same
Regulation No.	21 CFR 872.3820	21 CFR 872.3820	Same
Class	II	II	Same
Intended 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. C-Root SP Injectable Root Canal Bioceramic Sealer is suitable for use in the single cone and lateral condensation technique.	* 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. iRoot SP is suitable for use in the single cone and lateral condensation technique.	Same
Prescription Use	Yes	Yes	Same
Basic Chemical Composition	Zirconium Oxide, Strontium Silicates, Calcium Phosphates, Calcium Hydroxide, Tantalum Oxide and Filler Agents.	Zirconium Oxide, Calcium Silicates, Calcium Hydroxide, Calcium Phosphate Monobasic and Filler Agents	Similar
Performance Standard Conformance	Conformed to ISO 6876 and conformed to Technical Requirements of "Injectable Root Canal Bioceramic Sealer"adding Appearance,Dimensional change following setting,pH.	Conformed to ISO 6876	Same
Treatment Site	Root canal following vital pulp-extirpation	Root canal following vital pulp-extirpation	Same

Sterile	Non-sterile	Non-sterile	Same
Biocompatibility	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.	Comply with ISO 10993-1, FDA Guidance	Same
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Same

Analysis:

iRoot SP Root Canal Sealer was identified as the predicate device due to the subject device having similar materials and delivery form (i.e. premixed ready-to-use injectable paste) to the predicate. The predicate device is composed of Zirconium oxide, a radiopaque agent and thickening agents as does the subject device. The subject device uses strontium silicates, the predicate device uses calcium silicates, strontium silicates and calcium silicates are all belong to silicate and can be set and harden upon the moisture in the dentin. Also, strontium silicates have better radiation resistance than calcium silicates. Also, the biocompatibility testing completed in alignment ISO 10993-1 and ISO 7405:2018 respectively demonstrate that any material differences between the subject device and predicate device do not raise any new questions as to safety and effectiveness.

Performance comparison testing was conducted to the predicate device and current device to compare their performance according to the Technical Requirements of “Injectable Root Canal Bioceramic Sealer”, which is identical to ISO 6876,and at the same time, adding the requirements on Appearance, Dimensional change following setting and pH. And the comparison testing results shown both the subject device and the predicate device are complied with Technical Requirements of “Injectable Root Canal Bioceramic Sealer”.

Therefore, it is concluded that the subject device is substantially equivalent to the predicate device.

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the differences between the proposed device and the predicated device are insignificant in terms of substantial equivalence. The subject device is

substantially equivalent to the predicate device in K080917.