May 28, 2024

Enpuno Biotechnology Co., Ltd
Hao He
General Manager
No. 201, Haiping Park Production Plant3, No.229, Guyuan Road
Changsha High-tech Development Zone Changsha City, Hunan 410205
CHINA

Re: K240304
Trade/Device Name: Injectable Root Canal Bioceramic Sealer (NR SP-0.5, NR SP-1, NR SP-2, NR SP-3, NR SP-5)
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: April 29, 2024
Received: April 29, 2024

Dear Hao He:

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,

Michael E. Adjodha -S

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.

Submission Number *(if known)*

K240304

Device Name

Injectable Root Canal Bioceramic Sealer (NR SP-0.5, NR SP-1, NR SP-2, NR SP-3, NR SP-5)

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.
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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K240304

Section 4 - 510(k) Summary

Date of Summary Preparation: January 24, 2024
Update the Date：March 16 2024

1. Submitter's Identifications

Submitter's Name: Enpuno Biotechnology Co., Ltd
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2. Correspondent's Identifications

Correspondent's Name: Guangzhou Junyi Information Technology Co., Ltd.
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3. Name of the Device

Device Classification Name: Resin, Root Canal Filling
Regulation Description: Root Canal Filling Resin
Trade Name: Injectable Root Canal Bioceramic Sealer（NR SP-0.5, NR SP-1, NR SP-2, NR SP-3, NR SP-5）
Regulation Medical Specialty: Dental
Review Panel: Dental
Product Code: KIF
Regulation Number: 21 CFR 872.3820
Device Classification: Class II

4. The Predicate Devices

Predicate device: K212983 Injectable Root Canal Bioceramic Sealer Beijing C-Root Dental Medical Devices Co., LTD.

5. Device Description

NRSP 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. NRSP is an insoluble, radiopaque and aluminum-free material based on a strontium silicates composition, which requires the presence of water to set and harden. NRSP does not shrink during setting and demonstrates excellent physical properties. NRSP is packaged in a preloaded syringe and is supplied with disposable Intra Canal tips. NRSP may be delivered into the canal via the disposable tips or it can be delivered via traditional methods. NRSP Injectable Root Canal Bioceramic Sealer is available in three preloaded syringe mode that provide different in specification in5g,3g,2g,1g and 0.5g. The only difference between the types are the net weight.

Root canal filling paste is a pre mixed paste material consisting of an inorganic powder system and an organic mixed liquid. It can solidify in a humoral environment, effectively seal the root tip, and has good biocompatibility; The curing time is stable and less affected by root canal moisture and humidity; It has excellent X-ray resistance, fluidity, antibacterial properties, non staining of teeth, and no irritation.

The performance of the Injectable Root Canal Bioceramic Sealer conforms to ISO 6876:2012 Dentistry - Root canal sealing materials.

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.

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

7. Summary of Substantial Equivalence

Table 1 Comparison to Predicate Device

	Proposed Device	**Predicate device**	**Comparison**
510k Number		K212983	------
Product Code	KIF	KIF	Same
Regulation No.	21 CFR 872.3820	21 CFR 872.3820	Same
Class	II	II	Same
Proprietary Name	Injectable Root Canal Bioceramic Sealer	Injectable Root Canal Bioceramic Sealer	------

Model:	NR SP-0.5, NR SP-1, NR SP-2, NR SP-3, NR SP-5	C-Root SP	------
Manufacturer	Enpuno Biotechnology Co., Ltd	Beijing C-Root Dental Medical Devices Co., LTD.	------
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. 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. Injectable Root Canal Bioceramic Sealer 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, Strontium Silicates, Calcium Phosphates, Calcium Hydroxide, Tantalum Oxide and Filler Agents.	Same
Performance Standard Conformance	Conformed to ISO 6876 and conformed to Technical Requirements of	Conformed to ISO 6876 and conformed to Technical Requirements of	Same

	"Injectable Root Canal Bioceramic Sealer" adding Appearance, Dimensional change following setting, pH.	"Injectable Root Canal Bioceramic Sealer" adding Appearance, Dimensional change following setting, pH.	
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 10993-1:2018, FDA Guidance, tests included cytotoxicity, irritation, sensitization, acute systemic toxicity, subchronic systemic toxicity test, implantation effect , endodontic usage test , Ames test and TK test.	Same
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Same
Discussion for Substantially Equivalent (SE)	The proposed device is essentially identical to the predicate devices in terms of indication for use, design between our device and the predicate devices.		

8. Summary of Non-Clinical Testing

Bench testing was performed per ISO 6876:2012 and internal procedures to ensure that the Injectable Root Canal Bioceramic Sealer met its specifications. All tests were verified to meet acceptance criteria. Test results on Appearance, Loading capacity, Flow, Setting time, Film thickness, Dimensional change following setting, Solubility and disintegration, Radio-opacity, PH, Heavy metal content and Microorganism of the

subject device are very similar to predicate device. Biocompatibility testing was performed to verify the equivalent safety of the materials that are used.

According to ISO 10993-1:2018, we evaluated and conducted the compatibility test for the proposed device. The following table shows the biocompatibility testing results.

Table 2 Biocompatibility testing

Item	Proposed device	Result
In Vitro Cytotoxicity Test with L-929 Mouse Fibroblast Cells MTT Cytotoxicity Test (ISO 10993-5:2009)	Under the condition of this study , the relative cell viability value of test article Injectable Root Canal Bioceramic Sealer is 4.2% which is lower than 70% , with potential cytotoxicity.	Pass
Skin sensitization tests-Guinea pig maximization test (GPMT) (ISO 10993-10:2010)	Under the conditions of this test , none of the animals from test and control groups was observed with a sensitization response greater than " 1 " during 24h and 48h observation time after challenge . The test article Injectable Root Canal Bioceramic Sealer showed no evidence of causing skin sensitization.	Pass
Salmonella typhimurium reverse mutation assay (Ames test) (ISO 10993-3:2014)	In this test . the test article did not induce substantial increases in reversion mutation rates of salmonella typhimurium. Under the conditions of this test . the test article Iniectable Root Canal Bioceramic Sealer is considered non-mutagenic effect.	Pass
Mouse lymphoma cells (TK) gene mutation test (ISO 10993-3:2014)	Under the condition of this study , the results of mouse lymphoma cell (TK) gene mutation test of the test article Injectable Root Canal Bioceramic Sealer were negative , and considered non-mutagenic effect.	Pass
Acute Systemic Toxicity Test (ISO 10993-11:2017)	Under the conditions of this test , the test article Injectable Root Canal Bioceramic Sealer didn't lead to the death of test animals or any signs of toxicity for test animals , which showed no acute toxicity with a dose of 2000mg / kg	Pass
Subchronic systemic toxicity Test (ISO 10993-11:2017)	Under the conditions of this study , there was no evidence of subchronic systemic toxicity from the test article Injectable Root Canal Bioceramic Sealer.	Pass
Bone implant test (ISO 10993-6:2016)	Under the conditions of this experiment , the test article Injectable Root Canal Bioceramic Sealer (cured) had new bone formation within the test period (4 weeks , 26weeks) , and the bone tissue reaction ranged from no reaction to slight tissue reaction showing no significant difference from the control group.	Pass
Pyrogen test	Under the conditions of this study , the test article	Pass

(ISO10993-11:2017)	Injectable Root Canal Bioceramic Sealer showed no evidence of causing pyrogenic reaction	
Endodontic usage Test (ISO 7405-2018, MOD)	Histological evaluation : At the time period of 28 days , among the 10 test specimens , 10 specimens showed no inflammation . Among the 5 control specimens , 5 specimens showed no inflammation . At the time period of 90 days , among the 10 test specimens , 10 specimens showed no inflammation ; among the 5 control specimens , 5 specimens showed no inflammation . No mild , moderate or severe inflammatory reactions were observed in the experimental group and control group during the long-term and short-term period . X-ray examination showed no abnormalities . There was no significant difference in clinical and histological performance between the test group and the control group. Results and conclusions apply only to the test article . No further evaluation of these results is made by Dental Medical Devices Testing Center of Peking University School of Stomatology . Any extrapolation of these data to other samples is the responsibility of the sponsor . All procedures were conducted in conformance with Dental Medical Devices Testing Center of Peking University School of Stomatology Quality System.	Pass

Note: Testing were Performed on Injectable Root Canal Bioceramic Sealer NR SP-2, (As NR SP-2 is the most widely sold and representative specification in the market), to cover the regular and Injectable Root Canal Bioceramic Sealer.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that subject device Injectable Root Canal Bioceramic Sealer is as safe and effective as the predicate device. Injectable Root Canal Bioceramic Sealer is substantial equivalent to the legally marketed predicate device K212983 Injectable Root Canal Bioceramic Sealer.