June 11. 2025

Enpuno Co., Ltd
Chengfa Huang
RA Manager
No. 201, Haiping Park Production Plant3, No.229, Guyuan Road
Changsha High-tech Development Zone
Changsha City, Hunan 410205
China

Re: K250710
Trade/Device Name: Injectable Root Canal Bioceramic Sealer (nRoot SP)
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: May 13, 2025
Received: May 13, 2025

Dear Chengfa Huang:

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,

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)*

K250710

Device Name

Injectable Root Canal Bioceramic Sealer（nRoot 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.
Injectable Root Canal Bioceramic Sealer（nRoot SP） 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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Section 4 - 510(k) Summary - K250710

Date of Summary Preparation: March 24, 2025
Update the Date：June 09, 2025

1. Submitter's Identifications

Submitter's Name: Enpuno Biotechnology Co., Ltd
Address: No. 201, Haiping Park Production Plant3, No.229, Guyuan Road Changsha High-tech Development Zone Changsha City, Hunan Province, China.
Zip Code: 410205
Contact Person: Chengfa Huang
Contact Title: RA manager
Contact E-mail Address: 271516734@qq .com
Tel: +86-731-84257959

2. Correspondent's Identifications

Correspondent's Name: Guangzhou Junyi Information Technology Co., Ltd.
Address: Room 304, Building A, No. 62 Nanyun 2nd Road, Science Town, Huangpu District, Guangzhou City, Guangdong, 510663, China.
ZIP Code: 510663
Contact Person: Shanfeng Jiang
Contact Title: Regulation Control Manager
Contact E-mail Address: jiang13620586569@126.com
Tel: +86-20-82329549
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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（nRoot SP）
Model: 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: K240304 Injectable Root Canal Bioceramic Sealer (NR SP-0.5, NR SP-1, NR SP-2, NR SP-3, NR SP-5) Enpuno Biotechnology Co., Ltd

5. Device Description

Injectable Root Canal Bioceramic Sealer（nRoot SP）is a convenient premixed ready-to-use injectable white hydraulic cement paste developed for permanent root canal filling and sealing applications. nRoot SP is an insoluble, radiopaque on a calcium silicate composition, which requires the presence of water to set and harden. nRoot SP does not shrink during setting and demonstrates excellent physical properties.

nRoot SP is packaged in a preloaded syringe and is supplied with disposable Intra Canal tips. nRoot SP may be delivered into the canal via the disposable tips or it can be delivered via traditional methods. Injectable Root Canal Bioceramic Sealer（nRoot SP） is available in five preloaded syringe mode that provide different in specification in 5g,3g,2g,1g and 0.5g. The only difference between the types are the net weight.

The performance of the Injectable Root Canal Bioceramic Sealer（nRoot SP） 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（nRoot SP）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	K250710	K240304	------
Product Code	KIF	KIF	Same
Regulation No.	21 CFR 872.3820	21 CFR 872.3820	Same
Class	**Class** II	**Class** II	Same
Proprietary Name	Injectable Root Canal Bioceramic Sealer（nRoot SP）	Injectable Root Canal Bioceramic Sealer (NR SP-0.5, NR SP-1, NR SP-2, NR SP-3, NR SP-5)	------
Model:	NR SP-0.5, NR SP-1, NR SP-2, NR SP-3, NR SP-5	/	------

Manufacturer	Enpuno Biotechnology Co., Ltd	Enpuno Biotechnology 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（nRoot SP） 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 dioxide, Calcium silicates, Calcium hydroxide and Thickening agent.	Zirconium Oxide, Strontium Silicates, Calcium Phosphates, Calcium Hydroxide, Tantalum Oxide and Filler Agents.	Similar
Performance Standard Conformance	Conformed to ISO 6876 and conformed to Technical Requirements of "Injectable Root Canal Bioceramic Sealer（nRoot SP）" adding Appearance, Dimensional change following setting, pH.	Conformed to ISO 6876 and conformed to Technical Requirements of "Injectable Root Canal Bioceramic Sealer" adding Appearance, Dimensional change following setting, pH.	Same
Treatment Site	Root canal following vital pulp-extirpation	Conformed to ISO 6876	Same
Sterile	Non-sterile	Non-sterile	Same
Biocompatibility	Yes	Yes	Same
Use	Prescription / Hospital	Prescription / Hospital	Same

Delivery Forms	Single Paste	Single Paste	Same
Shelf Life	2 years	2 years	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 （nRoot SP）met its specifications. All tests were verified to meet acceptance criteria. Test results on Appearance, Loading capacity, Flow, Working time, 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.

Biocompatibility was addressed using FDA's Biocompatibility Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part: Evaluation and testing within a risk management process" and ISO 7405 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry.

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（nRoot SP） is as safe and effective as the predicate device. Injectable Root Canal Bioceramic Sealer（nRoot SP） is substantial equivalent to the legally marketed predicate device K240304 Injectable Root Canal Bioceramic Sealer.