September 25, 2025

Enpuno Biotechnology 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: K251465
Trade/Device Name: Root canal repair materials (nRoot BP)
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: August 25, 2025
Received: August 25, 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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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Respiratory, ENT, and Dental Devices
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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)*

K251465

Device Name

Root canal repair materials (nRoot BP)

Indications for Use *(Describe)*

Root canal repair materials（nRoot BP） 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) #: K251465

510(k) Summary

Prepared on: 2025-08-25

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Enpuno Biotechnology Co., Ltd
Applicant Address	No. 201, Haiping Park Production Plant3, No.229, Guyuan Road Changsha High-tech Development Zone Changsha City Hunan 410205 China
Applicant Contact Telephone	+86-73184257959
Applicant Contact	Mr. Chengfa Huang
Applicant Contact Email	jiang13620586569@126.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Root canal repair materials (nRoot BP)
Common Name	Root canal filling resin
Classification Name	Resin, Root Canal Filling
Regulation Number	872.3820
Product Code(s)	KIF, 21 CFR 872.3820

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K092715	IROOT BP PLUS	KIF

Device Description Summary

21 CFR 807.92(a)(4)

The root canal repair material is a pre mixed paste material containing an inorganic powder system and an organic mixed liquid. Can solidify in a bodily fluid environment and effectively repair root canals; Has excellent X-ray blocking properties, stable curing time, and does not stain teeth. nRoot BP is packaged in a preloaded syringe.
The performance of the Root canal repair materials conforms to ISO 6876:2012 Dentistry - Root canal sealing materials.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Root canal repair materials （nRoot BP） 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

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same between proposed device and predicate device .

Technological Comparison 21 CFR 807.92(a)(6)

The proposed device is essentially identical to the predicate devices in terms of indication for use, design between our device and the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The bench test include tests for
1. Type Test by the third test party:
There are one type test reports, respectively:
Item Test results Report No.
Physical and chemical performance testing ISO 6876 The physical and chemical properties of the samples are complied with ISO 6876:2012. CHTT24110009
CHTT25080250

The test results of the components, Appearance, Deliverable volume, Setting time, Dimensional changes after setting, Solubility and disintegration, Compressive strength, pH, Acid-soluble arsenic and lead content , Radio-opacity and Microbiologic al indicator etc. of the Device under test are very similar to those of the predicate device.

The Root canal repair materials （nRoot BP）(Tricalcium silicate, dicalcium silicate, zirconium oxide, Calcium Hydroxide, Calcium Phosphate and Thickening Agent.) of the proposed device is basically the same as the predicate device.

2. Performance Test
Factory Performance Test, including: Appearance, Deliverable volume, Setting time, Dimensional changes after setting, Solubility and disintegration, Compressive strength, pH, Acid-soluble arsenic and lead content , Radio-opacity and Microbiologic al indicator, Packaging, Marks, labels and instructions.

Bench testing was performed per ISO 6876:2012 and internal procedures to ensure that the Root canal repair materials met its specifications. All tests were verified to meet acceptance criteria. Test results on Appearance, Deliverable volume, Setting time, Dimensional changes after setting, Solubility and disintegration, Compressive strength, pH, Acid-soluble arsenic and lead content , Radio-opacity and Microbiological indicator etc. of the Device under test are very similar to those of the predicate device. The biocompatibility of the subject device was addressed using FDA's Biocompatibility guidance document, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"" and ISO 7405 Dentistry — Evaluation of biocompatibility of medical devices used in dentistry .

The conclusions drawn from the nonclinical tests demonstrate that subject device Root canal repair materials （nRoot BP） is as safe and effective as the predicate device. Root canal repair materials （nRoot BP） is substantial equivalent to the legally marketed predicate device K092715 IROOT BP PLUS .