

K251465 Root canal repair materials (nRoot BP)Sep 25, 2025
135 days to decisionK251465 · Product code: **KIF** · DentalSource: <https://www.510kdatabase.net/k251465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	May 13, 2025
Decision date	Sep 25, 2025
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Enpuno Biotechnology Co., Ltd.
Location	Changsha High-Tech Development Zone Chan, CN
Contact	Chengfa Huang
510(k) history	2 submissions · 2 cleared · 2024-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251465/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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