

K240304 Injectable Root Canal Bioceramic Sealer (NR SP-0.5, NR SP-1, NR SP-2, NR SP-3, NR SP-5)May 28, 2024
116 days to decisionK240304 · Product code: **KIF** · Dental
Source: <https://www.510kdatabase.net/k240304/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Feb 2, 2024
Decision date	May 28, 2024
Days to decision	116 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	Hao He
510(k) history	2 submissions · 2 cleared · 2024-2025

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