

K250710 Injectable Root Canal Bioceramic Sealer (nRoot SP)Jun 11, 2025
93 days to decisionK250710 · Product code: **KIF** · DentalSource: <https://www.510kdatabase.net/k250710/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Mar 10, 2025
Decision date	Jun 11, 2025
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Enpuno Co., Ltd.
Location	Changsha, CN
Contact	Chengfa Huang
510(k) history	1 submissions · 1 cleared · 2025-2025

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