

K240365 Bioceramic Root Repair Material (C-Root BP)May 10, 2024
94 days to decisionK240365 · Product code: **KIF** · DentalSource: <https://www.510kdatabase.net/k240365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Feb 6, 2024
Decision date	May 10, 2024
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beijing C-Root Dental Medical Devices Co., Ltd.
Location	Beijing, CN
Contact	Bingmin Wu
510(k) history	2 submissions · 2 cleared · 2021-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240365/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026