

K212983 Injectable Root Canal Bioceramic SealerDec 8, 2021
82 days to decisionK212983 · Product code: **KIF** · DentalSource: <https://www.510kdatabase.net/k212983/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Sep 17, 2021
Decision date	Dec 8, 2021
Days to decision	82 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

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212983/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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