

K222992 iRoot BP Root Repair Material BioAggregate PasteNov 22, 2022
55 days to decisionK222992 · Product code: **KIF** · DentalSource: <https://www.510kdatabase.net/k222992/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Sep 28, 2022
Decision date	Nov 22, 2022
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	iRoot FS Fast Set Root Repair Material ;iRoot BP Plus Root Repair Material

APPLICANT

Company	Innovative Bioceramix, Inc.
Location	Vancouver, Bc, CA
Contact	Quanzu Yang
510(k) history	8 submissions · 8 cleared · 2006-2023

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