

**K130312 IROOT FM**Sep 18, 2014  
588 days to decisionK130312 · Product code: **KIF** · DentalSource: <https://www.510kdatabase.net/k130312/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Feb 7, 2013
Decision date	Sep 18, 2014
Days to decision	588 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innovative Bioceramix, Inc.</b>
Location	Vancouver, Bc, CA
Contact	QUANZU YANG
510(k) history	8 submissions · 8 cleared · 2006-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130312/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026