

**K082943 IROOT BP, MODEL IRBP 4609**Jan 6, 2009  
96 days to decisionK082943 · Product code: **KIF** · DentalSource: <https://www.510kdatabase.net/k082943/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Oct 2, 2008
Decision date	Jan 6, 2009
Days to decision	96 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/k082943/> 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