

**K091647 INJECTAFIL**Sep 21, 2009  
104 days to decisionK091647 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k091647/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jun 9, 2009
Decision date	Sep 21, 2009
Days to decision	104 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Apex Dental Materials, Inc.</b>
Location	Schaumburg, IL, US
Contact	CHRIS KULTON
510(k) history	15 submissions · 15 cleared · 2001-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091647/> 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 June 18, 2026