

**K160086 SHOFU Enamel Conditioner**Jul 21, 2016  
188 days to decisionK160086 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k160086/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jan 15, 2016
Decision date	Jul 21, 2016
Days to decision	188 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Shofu Dental Corporation</b>
Location	San Marcos, CA, US
Contact	MAURO MALZYNER
510(k) history	38 submissions · 38 cleared · 2011-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160086/> 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 2, 2026