

**K182869 Fit SA**Jan 9, 2019  
89 days to decisionK182869 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k182869/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Oct 12, 2018
Decision date	Jan 9, 2019
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	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/k182869/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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