

**K200470 Shofu Block HC Hard**Feb 5, 2021  
345 days to decisionK200470 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k200470/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Feb 26, 2020
Decision date	Feb 5, 2021
Days to decision	345 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/k200470/> 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 13, 2026