

**K252808 Glaslonomer FX-LC**Dec 9, 2025  
97 days to decisionK252808 · Product code: **EMA** · Dental  
Source: <https://www.510kdatabase.net/k252808/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Sep 3, 2025
Decision date	Dec 9, 2025
Days to decision	97 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	Malzyner Mauro
510(k) history	38 submissions · 38 cleared · 2011-2025

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