

K222253 Glaslonomer FX ULTRASep 22, 2022
57 days to decisionK222253 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k222253/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Jul 27, 2022
Decision date	Sep 22, 2022
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shofu Dental Corporation
Location	San Marcos, CA, US
Contact	Mauro Malzyner
510(k) history	38 submissions · 38 cleared · 2011-2025

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