

K182854 GC FujiCEM 2 (Improved)Jul 11, 2019
274 days to decisionK182854 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k182854/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Oct 10, 2018
Decision date	Jul 11, 2019
Days to decision	274 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	GC America, Inc.
Location	Alsip, IL, US
Contact	Mark Heiss
510(k) history	125 submissions · 125 cleared · 1993-2025

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