

K172382 GC Fuji DirectApr 2, 2018
237 days to decisionK172382 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k172382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Aug 8, 2017
Decision date	Apr 2, 2018
Days to decision	237 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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