

K254109 G-CEM UNIVERSALMay 18, 2026
150 days to decisionK254109 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k254109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Dec 19, 2025
Decision date	May 18, 2026
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GC America, Inc.
Location	Alsip, IL, US
Contact	Futoshi Fusejima
510(k) history	126 submissions · 126 cleared · 1993-2026

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