

K250953 EQUIA LC ONESep 19, 2025
175 days to decisionK250953 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k250953/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Mar 28, 2025
Decision date	Sep 19, 2025
Days to decision	175 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	125 submissions · 125 cleared · 1993-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250953/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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