

K980682 FUJI IIApr 3, 1998
39 days to decisionK980682 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k980682/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Feb 23, 1998
Decision date	Apr 3, 1998
Days to decision	39 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980682/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026