

**K193484 GC Fuji Triage EP**Jul 2, 2020  
198 days to decisionK193484 · Product code: **EMA** · Dental  
Source: <https://www.510kdatabase.net/k193484/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Dec 17, 2019
Decision date	Jul 2, 2020
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193484/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026