

K080478 GRADIA FORTEJun 5, 2008
104 days to decisionK080478 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k080478/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Feb 22, 2008
Decision date	Jun 5, 2008
Days to decision	104 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080478/> 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 25, 2026