

K091388 GCUC-505

Jul 22, 2009
72 days to decision

K091388 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k091388/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	May 11, 2009
Decision date	Jul 22, 2009
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

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.net

Device record: <https://www.510kdatabase.net/k091388/> 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 22, 2026