

K133824 CERASMARTMar 14, 2014
87 days to decisionK133824 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k133824/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Dec 17, 2013
Decision date	Mar 14, 2014
Days to decision	87 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.netDevice record: <https://www.510kdatabase.net/k133824/> 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 7, 2026