

K082434 GDLS-200Nov 14, 2008
81 days to decisionK082434 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k082434/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Aug 25, 2008
Decision date	Nov 14, 2008
Days to decision	81 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

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