

**K151541 G-Fix**Oct 9, 2015  
123 days to decisionK151541 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k151541/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jun 8, 2015
Decision date	Oct 9, 2015
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151541/> 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 June 3, 2026