

**K143140 G-Premio BOND**Apr 20, 2015  
168 days to decisionK143140 · Product code: **KLE** · Dental  
Source: <https://www.510kdatabase.net/k143140/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Nov 3, 2014
Decision date	Apr 20, 2015
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>GC America, Inc.</b>
Location	Alsip, IL, US
Contact	Dr. 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/k143140/> 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 4, 2026