

**K200798 G-CEM ONE**Nov 24, 2020  
243 days to decisionK200798 · Product code: **EMA** · Dental  
Source: <https://www.510kdatabase.net/k200798/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Mar 26, 2020
Decision date	Nov 24, 2020
Days to decision	243 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/k200798/> 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 May 14, 2026