

**K093575 GLUMA DESENSITIZER POWER GEL**Mar 5, 2010  
107 days to decisionK093575 · Product code: **LBH** · Dental  
Source: <https://www.510kdatabase.net/k093575/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	Nov 18, 2009
Decision date	Mar 5, 2010
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Heraeus Kulzer, LLC</b>
Location	South Bend, IN, US
Contact	CHERYL V ZIMMERMAN
510(k) history	11 submissions · 11 cleared · 2009-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093575/> 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 9, 2026