

**K090519 VANISH VARNISH, 5% SODIUM FLUORIDE VARNISH,  
MODEL 12245, VANISH VARNISH, 5% FLUORIDE VARNISH,  
MODEL 12247**Apr 15, 2009  
48 days to decisionK090519 · Product code: **LBH** · Dental  
Source: <https://www.510kdatabase.net/k090519/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Varnish, Cavity (LBH)
Date received	Feb 26, 2009
Decision date	Apr 15, 2009
Days to decision	48 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3M Company</b>
Location	White City, OR, US
Contact	KAREN O'MALLEY
Website	<a href="http://www.3m.com/">http://www.3m.com/</a>
510(k) history	331 submissions · 322 cleared · 1976-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090519/> 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 23, 2026