

**K113146 PCXX VARNISH**Jan 23, 2012  
91 days to decisionK113146 · Product code: **LBH** · Dental  
Source: <https://www.510kdatabase.net/k113146/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Varnish, Cavity (LBH)
Date received	Oct 24, 2011
Decision date	Jan 23, 2012
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ross Healthcare, Inc.</b>
Location	Blaine, WA, US
Contact	MARC N ROSS
510(k) history	1 submissions · 1 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113146/> 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 15, 2026