

**K141422 PROFLUORO FLUORIDE VARNISH**Sep 30, 2014  
123 days to decisionK141422 · Product code: **LBH** · Dental  
Source: <https://www.510kdatabase.net/k141422/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	May 30, 2014
Decision date	Sep 30, 2014
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pac-Dent International, Inc.</b>
Location	Walnut, CA, US
Contact	WENYING ZHU
510(k) history	9 submissions · 9 cleared · 2013-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k141422/> 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 31, 2026