

**K153334 Oral-B 5% Sodium Fluoride Varnish**May 20, 2016  
183 days to decisionK153334 · Product code: **LBH** · Dental  
Source: <https://www.510kdatabase.net/k153334/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	Nov 19, 2015
Decision date	May 20, 2016
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Young Dental Manufacturing Co. 1, LLC</b>
Location	Mchenry, IL, US
Contact	Sarah Moore
510(k) history	16 submissions · 16 cleared · 1977-2025

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