

K132109 ENAMELASTNov 1, 2013
116 days to decisionK132109 · Product code: **LBH** · Dental
Source: <https://www.510kdatabase.net/k132109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	Jul 8, 2013
Decision date	Nov 1, 2013
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ultradent Products Inc. / Oratech, LLC
Location	Salt Lake City, UT, US
Contact	KAREN KAKUNES
510(k) history	2 submissions · 2 cleared · 2013-2013

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