

K013411 PULPDENT CAVITY PREPARATION IVDec 12, 2001
58 days to decisionK013411 · Product code: **LBH** · Dental
Source: <https://www.510kdatabase.net/k013411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	Oct 15, 2001
Decision date	Dec 12, 2001
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pulpdent Corp.
Location	Watertown, MA, US
Contact	KENNETH J BERK
510(k) history	78 submissions · 78 cleared · 1990-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013411/> Data sourced from FDA 510(k) public records (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. - Generated July 2, 2026