FDA 510(k) Premarket Notification

K013411 PULPDENT CAVITY PREPARATION IV

CLEARED

Dec 12, 2001
58 days to decision

K013411 · 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