

K090106 PRELUDE ONEMar 31, 2009
89 days to decisionK090106 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k090106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Jan 1, 2009
Decision date	Mar 31, 2009
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Danville Materials, Inc.
Location	San Ramon, CA, US
Contact	LINDSAY TILTON
510(k) history	11 submissions · 11 cleared · 2001-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090106/> 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 June 13, 2026