

**K964525 PRIME & BOND 2.1 M.P. DENTIN/ENAMEL BONDING
AGENT W/ACTIVATOR**Jan 22, 1997
71 days to decisionK964525 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k964525/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Nov 12, 1996
Decision date	Jan 22, 1997
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentsply Intl.
Location	Walker, MI, US
Contact	P. JEFFERY LEHN
510(k) history	279 submissions · 279 cleared · 1976-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964525/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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