

**K951864 PRIME & BOND DIRECT COMPOSITE BONDING
AGENT**May 23, 1995
32 days to decisionK951864 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k951864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Apr 21, 1995
Decision date	May 23, 1995
Days to decision	32 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951864/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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