FDA 510(k) Premarket Notification

K012440 MODIFICATION TO CLEARFIL LINER BOND 2V

CLEARED

Sep 5, 2001
36 days to decision

K012440 · Product code: **KLE** · Dental
Source: https://www.510kdatabase.net/k012440/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Jul 31, 2001
Decision date	Sep 5, 2001
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kuraray Medical, Inc.**
Location	New York, NY, US
Contact	MASAYA SASAKI
510(k) history	42 submissions · 42 cleared · 2001-2012