

K021427 CLEARFIL SA PRIMERJun 7, 2002
35 days to decisionK021427 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k021427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	May 3, 2002
Decision date	Jun 7, 2002
Days to decision	35 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k021427/> 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 15, 2026