

K081583 CLEARFIL SA CEMENTJul 28, 2008
53 days to decisionK081583 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k081583/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Jun 5, 2008
Decision date	Jul 28, 2008
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081583/> 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