FDA 510(k) Premarket Notification

K081583 CLEARFIL SA CEMENT

CLEARED

Jul 28, 2008
53 days to decision

K081583 · 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