FDA 510(k) Premarket Notification

K130223 RMGI FILL

CLEARED

Mar 29, 2013
59 days to decision

K130223 · Product code: **EMA** · Dental
Source: https://www.510kdatabase.net/k130223/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Jan 29, 2013
Decision date	Mar 29, 2013
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pulpdent Corporation**
Location	Watertown, MA, US
Contact	KENNETH J BERK
510(k) history	32 submissions · 32 cleared · 2002-2021