FDA 510(k) Premarket Notification

K083516 PERIOGENIX

CLEARED

Feb 20, 2009
86 days to decision

K083516 · Product code: **EMA** · Dental
Source: https://www.510kdatabase.net/k083516/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Nov 26, 2008
Decision date	Feb 20, 2009
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Oroscience, Inc.**
Location	Palo Alto, CA, US
Contact	MARY MCNAMARA
510(k) history	2 submissions · 2 cleared · 2008-2009