

K083398 CERCOM CEMENTJan 26, 2009
70 days to decisionK083398 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k083398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Nov 17, 2008
Decision date	Jan 26, 2009
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Denali R&D Corporation
Location	Hanover, MA, US
Contact	JAN G STANNARD
510(k) history	2 submissions · 2 cleared · 2009-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083398/> 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 23, 2026