

K070702 FUSION RESIN CEMENT AND CORE KITMay 10, 2007
58 days to decisionK070702 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k070702/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Mar 13, 2007
Decision date	May 10, 2007
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Denali Corporation
Location	Hanover, MA, US
Contact	JAN G STANNARD
510(k) history	9 submissions · 9 cleared · 2007-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k070702/> 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 3, 2026