

K011211 FLOWABLE COMPOSITE/ ECUFLOW/ LUXAFLOWJun 18, 2001
60 days to decisionK011211 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k011211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Apr 19, 2001
Decision date	Jun 18, 2001
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dmg USA, Inc.
Location	Ayer, MA, US
Contact	PAMELA PAPINEAU
510(k) history	28 submissions · 28 cleared · 2000-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011211/> 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 July 1, 2026