

K110859 METAL OPAQUERJun 23, 2011
87 days to decisionK110859 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k110859/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Mar 28, 2011
Decision date	Jun 23, 2011
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Apex Dental Materials, Inc.
Location	Schaumburg, IL, US
Contact	CHRIS KULTON
510(k) history	15 submissions · 15 cleared · 2001-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110859/> 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 18, 2026