

K153249 Pulpdent Solo Flowable Composite with MCPApr 1, 2016
144 days to decisionK153249 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k153249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Nov 9, 2015
Decision date	Apr 1, 2016
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pulpdent Corporation
Location	Watertown, MA, US
Contact	Kenneth J Berk
510(k) history	32 submissions · 32 cleared · 2002-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153249/> 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 May 14, 2026