

K210045 ACTIVA PRESTO PACKSep 22, 2021
257 days to decisionK210045 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k210045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jan 8, 2021
Decision date	Sep 22, 2021
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Lewis Berk
Contact	Lewis Berk

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210045/> 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 13, 2026