

K161580 Premier SealantOct 18, 2016
132 days to decisionK161580 · Product code: **EBC** · Dental
Source: <https://www.510kdatabase.net/k161580/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Jun 8, 2016
Decision date	Oct 18, 2016
Days to decision	132 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Premier Dental Company Products
Location	Plymouth Meeting, PA, US
Contact	VINCENT D'ALESSANDRO
510(k) history	3 submissions · 3 cleared · 2015-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161580/> 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 28, 2026