

K141717 PACSEAL PIT & FISSURE SEALANTMar 9, 2015
257 days to decisionK141717 · Product code: **EBC** · Dental
Source: <https://www.510kdatabase.net/k141717/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Jun 25, 2014
Decision date	Mar 9, 2015
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pac-Dent International, Inc.
Location	Walnut, CA, US
Contact	WENYING ZHU
510(k) history	9 submissions · 9 cleared · 2013-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141717/> 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 31, 2026