

**K113818 EMBRACE WETBOND PIT AND FISSURE SEALANT,
LOW FILL**Mar 21, 2012
85 days to decisionK113818 · Product code: **EBC** · Dental
Source: <https://www.510kdatabase.net/k113818/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Dec 27, 2011
Decision date	Mar 21, 2012
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Puldent 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/k113818/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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