

**K122521 PREVENT SEAL**Jun 11, 2013  
295 days to decisionK122521 · Product code: **EBC** · Dental  
Source: <https://www.510kdatabase.net/k122521/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Aug 20, 2012
Decision date	Jun 11, 2013
Days to decision	295 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Itena Clinical</b>
Location	Laval, CA
Contact	LOUIS-PAUL MARIN
510(k) history	8 submissions · 8 cleared · 2013-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122521/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 1, 2026