

**K131396 WIRED MOUTH PROTECTOR (WMP)**Sep 30, 2013  
138 days to decisionK131396 · Product code: **PFL** · DentalSource: <https://www.510kdatabase.net/k131396/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intraoral, Dental Foam Protector (PFL)
Date received	May 15, 2013
Decision date	Sep 30, 2013
Days to decision	138 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Elba Laboratories, Inc.</b>
Location	Ferndale, MI, US
Contact	RICHARD A HAMER
510(k) history	1 submissions · 1 cleared · 2013-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131396/> 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 8, 2026