

**K100801 PUMA MODEL VERSION 1.0**Jun 18, 2010  
88 days to decisionK100801 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k100801/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Mar 22, 2010
Decision date	Jun 18, 2010
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Prowess, Inc.</b>
Location	Chico, CA, US
Contact	RACHEL SCARANO
510(k) history	9 submissions · 9 cleared · 2003-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100801/> 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 May 26, 2026