

**K153101 BladderScan Prime System**Nov 19, 2015  
24 days to decisionK153101 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k153101/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Oct 26, 2015
Decision date	Nov 19, 2015
Days to decision	24 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Verathon Incorporated</b>
Location	Bothell, WA, US
Contact	Rhonda M Kops
510(k) history	5 submissions · 5 cleared · 2007-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153101/> 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 16, 2026