

**K123209 SOFTVUE**Dec 19, 2013  
433 days to decisionK123209 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k123209/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Oct 12, 2012
Decision date	Dec 19, 2013
Days to decision	433 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Delphinus Medical Technologies, Inc.</b>
Location	Plymouth, MI, US
Contact	ANDREA N WALLEN
510(k) history	2 submissions · 2 cleared · 2013-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123209/> 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