

**K100363 ULTRA DCI MODEL 5000**May 21, 2010  
98 days to decisionK100363 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k100363/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Feb 12, 2010
Decision date	May 21, 2010
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ultrasound Medical Devices, Inc.</b>
Location	Ann Arbor, MI, US
Contact	PAUL KORTESOJA
510(k) history	2 submissions · 2 cleared · 2010-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100363/> 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 17, 2026