

**K992378 DIAGNOSTIC ULTRASOUND, MODEL 1.0**Sep 29, 1999  
75 days to decisionK992378 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k992378/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jul 16, 1999
Decision date	Sep 29, 1999
Days to decision	75 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Volumetrics Medical Imaging, Inc.</b>
Location	Durham, NC, US
Contact	JIM MUNDELL
510(k) history	2 submissions · 2 cleared · 1998-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k992378/> 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 19, 2026