

**K162972 ExactVu High Resolution Micro-Ultrasound System**Dec 2, 2016  
38 days to decisionK162972 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k162972/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Oct 25, 2016
Decision date	Dec 2, 2016
Days to decision	38 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Exact Imaging</b>
Location	Markham, CA
Contact	Karina Torres
510(k) history	1 submissions · 1 cleared · 2016-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162972/> 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