

**K111347 ISROBOT MONA LISA**Aug 12, 2011  
91 days to decisionK111347 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k111347/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	May 13, 2011
Decision date	Aug 12, 2011
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biobot Surgical Pte., Ltd.</b>
Location	Alexandria, VA, US
Contact	CHERITA JAMES
510(k) history	7 submissions · 7 cleared · 2011-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111347/> 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 26, 2026