

**K232320 iSR`obot Mona Lisa 2.0**Dec 21, 2023  
140 days to decisionK232320 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k232320/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 3, 2023
Decision date	Dec 21, 2023
Days to decision	140 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	Lim Yan Shin
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/k232320/> 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