

K203659 iSR'obot Mona Lisa 1.0Jul 8, 2021
205 days to decisionK203659 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k203659/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Dec 15, 2020
Decision date	Jul 8, 2021
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biobot Surgical Pte., Ltd.
Location	Alexandria, VA, US
Contact	Lim Yan Shin
510(k) history	7 submissions · 7 cleared · 2011-2023

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