

K161109 iSR'obot MRI-US FusionOct 6, 2016
169 days to decisionK161109 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k161109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 20, 2016
Decision date	Oct 6, 2016
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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