

**K223484 IGAR System (1001.A)**Jul 20, 2023  
244 days to decisionK223484 · Product code: **MOS** · Radiology  
Source: <https://www.510kdatabase.net/k223484/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Nov 18, 2022
Decision date	Jul 20, 2023
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Insight Medbotics, Inc.</b>
Location	Hamilton, CA
Contact	Paul Chipperton
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Ironstone Product Development</b>
Contact	Joel Ironstone

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223484/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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