

K232361 Promaxo MRI System IISep 5, 2023
29 days to decisionK232361 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k232361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Aug 7, 2023
Decision date	Sep 5, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Promaxo, Inc.
Location	Oakland, CA, US
Contact	Veronica Sanz
510(k) history	2 submissions · 2 cleared · 2021-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232361/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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