FDA 510(k) Premarket Notification

K232361 Promaxo MRI System II

CLEARED

Sep 5, 2023
29 days to decision

K232361 · 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