

K240944 Swoop® Portable MR Imaging® SystemJul 16, 2024
102 days to decisionK240944 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k240944/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Apr 5, 2024
Decision date	Jul 16, 2024
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hyperfine, Inc.
Location	Guildford, CT, US
Contact	Christine Kupchick
510(k) history	13 submissions · 13 cleared · 2021-2025

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