

K253489 Swoop® Portable MR Imaging® SystemDec 12, 2025
49 days to decisionK253489 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k253489/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Oct 24, 2025
Decision date	Dec 12, 2025
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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