

K250236 Swoop® Portable MR Imaging® System (V2)May 30, 2025
123 days to decisionK250236 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k250236/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jan 27, 2025
Decision date	May 30, 2025
Days to decision	123 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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