

K230208 Swoop® Portable MR Imaging System™Feb 22, 2023
28 days to decisionK230208 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k230208/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jan 25, 2023
Decision date	Feb 22, 2023
Days to decision	28 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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