

K223247 Swoop Portable MR Imaging SystemDec 6, 2022
46 days to decisionK223247 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k223247/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Oct 21, 2022
Decision date	Dec 6, 2022
Days to decision	46 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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