

K221923 Swoop Portable MR Imaging SystemJul 28, 2022
27 days to decisionK221923 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k221923/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jul 1, 2022
Decision date	Jul 28, 2022
Days to decision	27 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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