

K221393 Swoop Portable MR Imaging SystemJun 10, 2022
28 days to decisionK221393 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k221393/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	May 13, 2022
Decision date	Jun 10, 2022
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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