

**K251276 Swoop® Portable MR Imaging® System**May 21, 2025  
27 days to decisionK251276 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k251276/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Apr 24, 2025
Decision date	May 21, 2025
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hyperfine, Inc.</b>
Location	Guildford, CT, US
Contact	Christine Kupchick
510(k) history	13 submissions · 13 cleared · 2021-2025

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