

K211818 Swoop Point-of-Care Magnetic Resonance Imaging (POC MRI) Scanner SystemJul 7, 2021
26 days to decisionK211818 · Product code: LNH · Radiology
Source: <https://www.510kdatabase.net/k211818/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jun 11, 2021
Decision date	Jul 7, 2021
Days to decision	26 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211818/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026