

K212456 Swoop Point-of-Care Magnetic Resonance Imaging (POC MRI) Scanner SystemNov 17, 2021
104 days to decisionK212456 · Product code: LNH · Radiology
Source: <https://www.510kdatabase.net/k212456/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Aug 5, 2021
Decision date	Nov 17, 2021
Days to decision	104 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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