

K201722 Hyperfine Point-Of-Care Magnetic Resonance Imaging (POC MRI) Scanner SystemAug 11, 2020
49 days to decisionK201722 · Product code: LNH · Radiology
Source: <https://www.510kdatabase.net/k201722/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jun 23, 2020
Decision date	Aug 11, 2020
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hyperfine Research, Inc.
Location	Guildford, CT, US
Contact	Robert Fasciano
510(k) history	3 submissions · 3 cleared · 2020-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201722/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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