

K201039 HepaFat-AIDec 7, 2020
231 days to decisionK201039 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k201039/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Apr 20, 2020
Decision date	Dec 7, 2020
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Resonance Health Analysis Services Pty, Ltd.
Location	Irvine, CA, US
Contact	Alison Laws
510(k) history	7 submissions · 6 cleared · 2011-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201039/> 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