

K231459 HepaFatSmart (V2.0.0)Jun 20, 2023
32 days to decisionK231459 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k231459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	May 19, 2023
Decision date	Jun 20, 2023
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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