

K213668 SIGNA HeroJan 20, 2022
59 days to decisionK213668 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k213668/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 22, 2021
Decision date	Jan 20, 2022
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Healthcare (Ge Medical Systems, LLC)
Location	Waukesha, WI, US
Contact	Sandra Westphal
510(k) history	6 submissions · 6 cleared · 2013-2022

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