

K193282 SIGNA PremierApr 10, 2020
135 days to decisionK193282 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k193282/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 27, 2019
Decision date	Apr 10, 2020
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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