

K250379 SIGNA Prime EliteMar 17, 2025
34 days to decisionK250379 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k250379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Feb 11, 2025
Decision date	Mar 17, 2025
Days to decision	34 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ge Medical Systems, LLC
Location	Waukesha, WI, US
Contact	Glen Sabin
Website	https://www.gehealthcare.com
510(k) history	104 submissions · 104 cleared · 2003-2026

GE Medical Systems, LLC is a medical device manufacturer based in Waukesha, US. The company specializes in Radiology devices and solutions. GE Medical Systems has received FDA 510(k) clearances from total submissions. The company's regulatory focus is entirely on Radiology devices, with a clearance history spanning from 2003 to 2026. The latest clearance in 2026 demonstrates active regulatory engagement within the past two years. Recent cleared devices include advanced imaging systems such as the Photonova Spectra series, SIGNA™ product line, AIR Recon DL, Revolution Vibe...

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Device record: <https://www.510kdatabase.net/k250379/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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