

**K201615 SIGNA 7.0T**Oct 15, 2020  
122 days to decisionK201615 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k201615/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jun 15, 2020
Decision date	Oct 15, 2020
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Medical Systems, LLC</b>
Location	Waukesha, WI, US
Contact	Brian R. Zielski
Website	<a href="https://www.gehealthcare.com">https://www.gehealthcare.com</a>
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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