

K113490 OPTIMA MR450WJan 13, 2012
51 days to decisionK113490 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k113490/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Nuclear Magnetic Resonance Imaging (LNH) |
| Date received | Nov 23, 2011 |
| Decision date | Jan 13, 2012 |
| Days to decision | 51 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ge Medical Systems, LLC |
| Location | Waukesha, WI, US |
| Contact | ROBIN MARTIN |
| 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...
