

**K103238 1.5T OPTIMA MR430S**Feb 11, 2011  
101 days to decisionK103238 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k103238/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Traditional                                      |
| Device classification | System, Nuclear Magnetic Resonance Imaging (LNH) |
| Date received         | Nov 2, 2010                                      |
| Decision date         | Feb 11, 2011                                     |
| Days to decision      | 101 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        | NORMA LEMAY   |
| 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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