

K123522 OPTIMA MR450WMar 13, 2013
118 days to decisionK123522 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k123522/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Nuclear Magnetic Resonance Imaging (LNH) |
| Date received | Nov 15, 2012 |
| Decision date | Mar 13, 2013 |
| Days to decision | 118 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123522/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 15, 2026