

K091444 PERFSCAPEJul 20, 2009
66 days to decisionK091444 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k091444/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Nuclear Magnetic Resonance Imaging (LNH) |
| Date received | May 15, 2009 |
| Decision date | Jul 20, 2009 |
| Days to decision | 66 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Olea Medical |
| Location | Austin, TX, US |
| Contact | NEAL KOLBER |
| 510(k) history | 11 submissions · 11 cleared · 2009-2023 |

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