

**K063207 S-SCAN MRI SYSTEM**Nov 9, 2006  
17 days to decisionK063207 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k063207/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Special  |
| Device classification | System, Nuclear Magnetic Resonance Imaging (LNH) |
| Date received         | Oct 23, 2006                                     |
| Decision date         | Nov 9, 2006                                      |
| Days to decision      | 17 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Esaote, S.P.A.</b>                                       |
| Location       | Genoa, IT   |
| Contact        | CARRI GRAHAM  |
| Website        | <a href="https://www.esaote.com">https://www.esaote.com</a> |
| 510(k) history | 67 submissions · 67 cleared · 2003-2026                     |

Esaote, S.P.A. is a medical diagnostic imaging company based in Genoa, Italy. The company specializes in ultrasound, MRI, and healthcare IT solutions for clinical settings. Esaote has received FDA 510(k) clearances from total submissions since 2003. The company's regulatory portfolio is dominated by Radiology devices, representing 100% of its FDA submissions. Recent cleared devices include the MyLab ultrasound systems and Magnifico Open imaging platforms. The company remains actively engaged in FDA regulatory submissions, with the latest clearance in 2026. Esaote's produc...

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