FDA 510(k) Premarket Notification

**CLEARED**

# K252239 InVision™ 3T Recharge Operating Suite

Aug 6, 2025
20 days to decision

K252239 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k252239/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Nuclear Magnetic Resonance Imaging (LNH) |
| Date received | Jul 17, 2025 |
| Decision date | Aug 6, 2025 |
| Days to decision | 20 days |
| Third-party review | Yes |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Imris Imaging, Inc.** |
| Location | Chaska, MN, US |
| Contact | Disha Kabrawala |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Regulatory Technology Services, LLC** |
| Contact | Prithul Bom |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov