

K241429 ECHELON Synergy MRI SystemAug 13, 2024
84 days to decisionK241429 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k241429/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Nuclear Magnetic Resonance Imaging (LNH) |
| Date received | May 21, 2024 |
| Decision date | Aug 13, 2024 |
| Days to decision | 84 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|----------------------------------------|
| Company | Fujifilm Healthcare Corporation |
| Location | Kashiwa-Shi, JP |
| Contact | Chaitrali Kulkarni |
| 510(k) history | 6 submissions · 6 cleared · 2022-2024 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------------------------------|
| Consulting firm | FUJIFILM Healthcare Americas Corporation |
| Contact | Chaitrali Kulkarni |

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

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