FDA 510(k) Premarket Notification

K223426 ECHELON Synergy MRI system

CLEARED

Jul 13, 2023
241 days to decision

K223426 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k223426/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 14, 2022
Decision date	Jul 13, 2023
Days to decision	241 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Healthcare Corporation**
Location	Kashiwa-Shi, JP
Contact	Randy Vader
510(k) history	6 submissions · 6 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	**FUJIFILM Healthcare Americas Corporation**
Contact	Kotei Aoki

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