FDA 510(k) Premarket Notification

K240571 OASIS MRI System

CLEARED

Apr 12, 2024
43 days to decision

K240571 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k240571/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Feb 29, 2024
Decision date	Apr 12, 2024
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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