FDA 510(k) Premarket Notification

K233629 APERTO Lucent MRI System

CLEARED

May 10, 2024
179 days to decision

K233629 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k233629/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 13, 2023
Decision date	May 10, 2024
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Healthcare Americas Corporation**
Location	Lexington, MA, US
Contact	Duan Threats
510(k) history	12 submissions · 12 cleared · 2023-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k233629/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026