

K243647 Synapse PACS (7.5)Jun 30, 2025
216 days to decisionK243647 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k243647/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 26, 2024
Decision date	Jun 30, 2025
Days to decision	216 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	Kulkarni Chaitrali
510(k) history	12 submissions · 12 cleared · 2023-2025

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