

K254189 Synapse 3D Base Tools (V7.2)Apr 30, 2026
128 days to decisionK254189 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k254189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 23, 2025
Decision date	Apr 30, 2026
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Corporation
Location	Ashigara Kami-Gun, JP
Contact	Kulkarni Chaitrali
510(k) history	62 submissions · 62 cleared · 2018-2026

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