

**K254075 Synapse Lung Nodule AI**May 27, 2026  
160 days to decisionK254075 · Product code: **OEB** · Radiology  
Source: <https://www.510kdatabase.net/k254075/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lung Computed Tomography System, Computer-aided Detection (OEB)
Date received	Dec 18, 2025
Decision date	May 27, 2026
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Corporation</b>
Location	Ashigara Kami-Gun, JP
Contact	Chaitrali Kulkarni
510(k) history	63 submissions · 63 cleared · 2018-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>FUJIFILM Healthcare Americas Corporation</b>
Contact	Chaitrali Kulkarni

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

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