

**K261713 Synapse PACS (7.6.0)**Jun 18, 2026  
27 days to decisionK261713 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k261713/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	May 22, 2026
Decision date	Jun 18, 2026
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Healthcare Americas Corporation</b>
Location	Lexington, MA, US
Contact	Chaitrali Kulkarni
510(k) history	13 submissions · 13 cleared · 2023-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k261713/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 10, 2026