

K252539 Tempus PixelSep 3, 2025
22 days to decisionK252539 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k252539/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Aug 12, 2025
Decision date	Sep 3, 2025
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arterys, Inc.
Location	San Francisco, CA, US
Contact	Bethany Barrett
510(k) history	8 submissions · 8 cleared · 2016-2025

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