

**K250484 PIUR tUS inside**Jun 30, 2025  
131 days to decisionK250484 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k250484/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Feb 19, 2025
Decision date	Jun 30, 2025
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Piur Imaging GmbH</b>
Location	Vienna, AT
Contact	Milos Stojanovic
510(k) history	2 submissions · 2 cleared · 2024-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>JW Regulatory Consulting, LLC</b>
Contact	Jennifer Willner

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

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