

K240036 PIUR tUS InfinitySep 20, 2024
259 days to decisionK240036 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k240036/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jan 5, 2024
Decision date	Sep 20, 2024
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	JW Regulatory Consulting, LLC
Contact	Jennifer Willner

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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