

K241984 Hi-D Imaging 4TAVRApr 2, 2025
268 days to decisionK241984 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k241984/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 8, 2024
Decision date	Apr 2, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hi-D Imaging AG
Location	Winterthur, CH
Contact	Utku Gulan
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Veranex, Inc.
Contact	Taras Bouzakine

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

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