

K261535 Hi-D Imaging 4TAVR

Jul 20, 2026
73 days to decision

K261535 · Product code: QIH · Radiology
Source: <https://www.510kdatabase.net/k261535/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	May 8, 2026
Decision date	Jul 20, 2026
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hi-D Imaging AG
Location	Winterthur, CH
Contact	Utku Gulan
510(k) history	2 submissions · 2 cleared · 2025-2026