

K253835 Affinity

Jul 31, 2026
242 days to decision

K253835 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k253835/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 1, 2025
Decision date	Jul 31, 2026
Days to decision	242 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hermes Medical Solutions AB
Location	Stockholm, SE
Contact	Hanne Grinaker
510(k) history	17 submissions · 17 cleared · 2012-2026