

K250023 SMART PCFDSep 29, 2025
269 days to decisionK250023 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k250023/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jan 3, 2025
Decision date	Sep 29, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Disior, Ltd.
Location	Helsinki Uusimaa, FL, US
Contact	Markku Laitinen
510(k) history	6 submissions · 6 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	Paragon 28, Inc.
Contact	Kelsey Gibson

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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