FDA 510(k) Premarket Notification

K250023 SMART PCFD

CLEARED

Sep 29, 2025
269 days to decision

K250023 · 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	Markuu 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