

K243919 Voxel Dosimetry (00859873006226)Jul 30, 2025
222 days to decisionK243919 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k243919/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 20, 2024
Decision date	Jul 30, 2025
Days to decision	222 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hermes Medical Solutions AB
Location	Stockholm, SE
Contact	Hanne Grinaker
510(k) history	16 submissions · 16 cleared · 2012-2025

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