

K250367 CoLumboXMay 28, 2025
107 days to decisionK250367 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k250367/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Feb 10, 2025
Decision date	May 28, 2025
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smart Soft Healthcare AD
Location	Varna, BG
Contact	Nedelcho Georgiev
510(k) history	3 submissions · 3 cleared · 2022-2026

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