

K254015 CoLumbo C-SpineApr 1, 2026
107 days to decisionK254015 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k254015/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 15, 2025
Decision date	Apr 1, 2026
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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