

K241211 CoLumboAug 15, 2024
107 days to decisionK241211 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k241211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 30, 2024
Decision date	Aug 15, 2024
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smart Soft Healthcare
Location	Varna, BG
Contact	Nedelcho Georgiev
510(k) history	1 submissions · 1 cleared · 2024-2024

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