FDA 510(k) Premarket Notification

K220497 CoLumbo

CLEARED

Jun 23, 2022
121 days to decision

K220497 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k220497/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Feb 22, 2022
Decision date	Jun 23, 2022
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Lightsource Research, LLC**
Contact	Yu Zhao

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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