FDA 510(k) Premarket Notification

K240953 AI Platform 2.0 (AIP002)

CLEARED

Aug 5, 2024
119 days to decision

K240953 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k240953/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 8, 2024
Decision date	Aug 5, 2024
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	**Exo Imaging**
Location	Santa Clara, CA, US
Contact	Jacqueline Murray
510(k) history	2 submissions · 2 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	**Exo, Inc.**
Contact	Jacqueline Murray

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