FDA 510(k) Premarket Notification

K243391 AISight Dx

CLEARED

Jun 26, 2025
238 days to decision

K243391 · Product code: **QKQ** · Pathology
Source: https://www.510kdatabase.net/k243391/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digital Pathology Image Viewing And Management Software (QKQ)
Date received	Oct 31, 2024
Decision date	Jun 26, 2025
Days to decision	238 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	**PathAI, Inc.**
Location	Boston, MA, US
Contact	Hisani Madison
510(k) history	2 submissions · 2 cleared · 2022-2025