

K212361 NovoAug 11, 2022
377 days to decisionK212361 · Product code: **QKQ** · Pathology
Source: <https://www.510kdatabase.net/k212361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digital Pathology Image Viewing And Management Software (QKQ)
Date received	Jul 30, 2021
Decision date	Aug 11, 2022
Days to decision	377 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212361/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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