

K243391 AISight DxJun 26, 2025
238 days to decisionK243391 · 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243391/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026