

K241696 Ortho AIJan 2, 2025
204 days to decisionK241696 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k241696/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jun 12, 2024
Decision date	Jan 2, 2025
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ortho Ai, LLC
Location	New York, NY, US
Contact	Jonathan Vigdorichik
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241696/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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