

**K250330 3mensio Workstation**Nov 3, 2025  
271 days to decisionK250330 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k250330/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Feb 5, 2025
Decision date	Nov 3, 2025
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Pie Medical Imaging BV</b>
Location	Maastricht, NL
Contact	Annemiek Bouts
510(k) history	23 submissions · 23 cleared · 2001-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250330/> 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