FDA 510(k) Premarket Notification

K250330 3mensio Workstation

CLEARED

Nov 3, 2025
271 days to decision

K250330 · 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	**Pie Medical Imaging BV**
Location	Maastricht, NL
Contact	Annemiek Bouts
510(k) history	23 submissions · 23 cleared · 2001-2025