

K232147 CAAS WorkstationApr 9, 2024
265 days to decisionK232147 · Product code: **QHA** · Radiology
Source: <https://www.510kdatabase.net/k232147/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray Angiographic Imaging Based Coronary Vascular Simulation Software Device (QHA)
Date received	Jul 19, 2023
Decision date	Apr 9, 2024
Days to decision	265 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232147/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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