

K251355 X1-FFROct 17, 2025
170 days to decisionK251355 · Product code: **QHA** · Radiology
Source: <https://www.510kdatabase.net/k251355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray Angiographic Imaging Based Coronary Vascular Simulation Software Device (QHA)
Date received	Apr 30, 2025
Decision date	Oct 17, 2025
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spectrawave, Inc.
Location	Bedford, MA, US
Contact	Ankit Shah
510(k) history	6 submissions · 6 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251355/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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