FDA 510(k) Premarket Notification

K251355 X1-FFR

CLEARED

Oct 17, 2025
170 days to decision

K251355 · 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