

K221257 SpectraWAVE Imaging SystemFeb 28, 2023
302 days to decisionK221257 · Product code: **NQQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k221257/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	May 2, 2022
Decision date	Feb 28, 2023
Days to decision	302 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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