

K251198 HyperVue™ SoftwareJul 16, 2025
90 days to decisionK251198 · Product code: **NQQ** · CardiovascularSource: <https://www.510kdatabase.net/k251198/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Apr 17, 2025
Decision date	Jul 16, 2025
Days to decision	90 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/k251198/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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