

K230691 HyperVue™ Imaging SystemJun 7, 2023
86 days to decisionK230691 · Product code: **NQQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k230691/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Mar 13, 2023
Decision date	Jun 7, 2023
Days to decision	86 days
Third-party review	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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