

**K253101 HyperVue™ Imaging System - Integrated**Dec 15, 2025  
82 days to decisionK253101 · Product code: **NQQ** · CardiovascularSource: <https://www.510kdatabase.net/k253101/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Sep 24, 2025
Decision date	Dec 15, 2025
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253101/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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