

K243016 Starlight Imaging CatheterMar 20, 2025
174 days to decisionK243016 · Product code: **NQQ** · CardiovascularSource: <https://www.510kdatabase.net/k243016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Sep 27, 2024
Decision date	Mar 20, 2025
Days to decision	174 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

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