

**K121195 NVISION VLE IMAGING SYSTEM NVISION VLE
CATHETER**Jul 25, 2012
97 days to decisionK121195 · Product code: **NQQ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k121195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Apr 19, 2012
Decision date	Jul 25, 2012
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ninepoint Medical, Inc.
Location	Hillsborough, CA, US
Contact	CINDY DOMECUS
510(k) history	8 submissions · 2 cleared · 2011-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121195/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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