

**K182261 NvisionVLE Imaging System, NvisionVLE Optical Probe**

Oct 16, 2018  
56 days to decision

K182261 · Product code: **NQQ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k182261/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Special
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Aug 21, 2018
Decision date	Oct 16, 2018
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ninepoint Medical, Inc.</b>
Location	Hillsborough, CA, US
Contact	Eman Namati
510(k) history	8 submissions · 2 cleared · 2011-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k182261/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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