

**K153479 NvisionVLE Imaging Console, NvisionVLE Marking Probe, 20mm balloon, NvisionVLE Marking Probe, 17mm balloon, NvisionVLE Marking Probe, 14mm balloon, NvisionVLE Inflation System**Feb 16, 2016  
76 days to decisionK153479 · Product code: **NQQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k153479/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Dec 2, 2015
Decision date	Feb 16, 2016
Days to decision	76 days
Third-party review	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/k153479/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026