

K182616 NvisionVLE Imaging System, NvisionVLE Optical Probe, NvisionVLE Inflation SystemNov 2, 2018
42 days to decisionK182616 · Product code: **NQQ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k182616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Sep 21, 2018
Decision date	Nov 2, 2018
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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