

K191117 NvisionVLE Low-profile Optical ProbeJul 19, 2019
84 days to decisionK191117 · Product code: **NQQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191117/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Apr 26, 2019
Decision date	Jul 19, 2019
Days to decision	84 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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