

K183320 Ilumien Optis, Optis Integrated, Optis MobileApr 2, 2019
123 days to decisionK183320 · Product code: **NQQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k183320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Nov 30, 2018
Decision date	Apr 2, 2019
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	St. Jude Medical (Now Abbott Medical)
Location	St. Paul, MN, US
Contact	Steve Vitale
510(k) history	2 submissions · 2 cleared · 2019-2019

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