

K153485 ENROUTE Transcarotid Neuroprotection SystemMar 10, 2016
98 days to decisionK153485 · Product code: **NTE** · Cardiovascular
Source: <https://www.510kdatabase.net/k153485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Carotid Catheter For Embolic Capture (NTE)
Date received	Dec 3, 2015
Decision date	Mar 10, 2016
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Silk Road Medical, Inc.
Location	Sunnyvale, CA, US
Contact	KRISTIN ELLIS
510(k) history	5 submissions · 5 cleared · 2013-2022

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