

K143072 ENROUTE Transcarotid Neuroprotection SystemFeb 9, 2015
105 days to decisionK143072 · Product code: **NTE** · Cardiovascular
Source: <https://www.510kdatabase.net/k143072/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Carotid Catheter For Embolic Capture (NTE)
Date received	Oct 27, 2014
Decision date	Feb 9, 2015
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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