

K230402 ENROUTE® Transcarotid Neuroprotection SystemApr 11, 2023
55 days to decisionK230402 · Product code: **NTE** · CardiovascularSource: <https://www.510kdatabase.net/k230402/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Temporary Carotid Catheter For Embolic Capture (NTE)
Date received	Feb 15, 2023
Decision date	Apr 11, 2023
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Silk Road Medical
Location	Sunnyvale, CA, US
Contact	Denise Aycox
510(k) history	1 submissions · 1 cleared · 2023-2023

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