

K200198 WIRIONMar 18, 2020
51 days to decisionK200198 · Product code: **NTE** · Cardiovascular
Source: <https://www.510kdatabase.net/k200198/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Carotid Catheter For Embolic Capture (NTE)
Date received	Jan 27, 2020
Decision date	Mar 18, 2020
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardiovascular Systems, Inc.
Location	Saint Paul, MN, US
Contact	Erika Huffman
510(k) history	26 submissions · 26 cleared · 2007-2022

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