

**K210282 WIRION Embolic Protection System**Mar 3, 2021  
30 days to decisionK210282 · Product code: **NTE** · CardiovascularSource: <https://www.510kdatabase.net/k210282/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Temporary Carotid Catheter For Embolic Capture (NTE)
Date received	Feb 1, 2021
Decision date	Mar 3, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210282/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026