

**K250385 Turbo-Elite Laser Atherectomy Catheter**Mar 13, 2025  
30 days to decisionK250385 · Product code: **MCW** · CardiovascularSource: <https://www.510kdatabase.net/k250385/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Feb 11, 2025
Decision date	Mar 13, 2025
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>Spectranetics</b>
Location	Colorado Springs, CO, US
Contact	Katie Adamski
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250385/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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