

K170059 Spectranetics Turbo-Elite Laser Atherectomy CathetersApr 7, 2017
91 days to decisionK170059 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k170059/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Jan 6, 2017
Decision date	Apr 7, 2017
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spectranetics, Inc.
Location	Colorado Springs, CO, US
Contact	Rebecca Spelich
510(k) history	17 submissions · 16 cleared · 2014-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170059/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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