

**K071226 8FR TURBO BOOSTER, GUIDE CATHETER, 7FR
TURBO BOOSTER, MODEL 518-063, 518-043**Jun 29, 2007
57 days to decisionK071226 · Product code: **PDU** · Cardiovascular
Source: <https://www.510kdatabase.net/k071226/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	May 3, 2007
Decision date	Jun 29, 2007
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spectranetics Corp.
Location	Colorado Springs, CO, US
Contact	MICHAEL K HANDLEY
510(k) history	24 submissions · 24 cleared · 1999-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071226/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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