

K112032 8FR TURBO - TANDEM SYSTEMOct 17, 2011
94 days to decisionK112032 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k112032/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jul 15, 2011
Decision date	Oct 17, 2011
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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