

K161333 TightRail Sub-C Rotating Dilator SheathJul 8, 2016
57 days to decisionK161333 · Product code: **DRE** · Cardiovascular
Source: <https://www.510kdatabase.net/k161333/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	May 12, 2016
Decision date	Jul 8, 2016
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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