

K142546 TightRail Rotating Dilator Sheath/TightRail Mini Dilator SheathSep 25, 2014
15 days to decisionK142546 · Product code: **DRE** · Cardiovascular
Source: <https://www.510kdatabase.net/k142546/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Sep 10, 2014
Decision date	Sep 25, 2014
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142546/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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