

**K150360 TightRail Rotating Dilator Sheath, TightRail Mini Rotating Dilator Sheath**

Mar 4, 2015  
20 days to decision

K150360 · Product code: **DRE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k150360/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Feb 12, 2015
Decision date	Mar 4, 2015
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k150360/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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