

**K223472 TightRail Guardian Motorized Dilator Sheath, 9 French
(575-009)**Dec 15, 2022
28 days to decisionK223472 · Product code: **DRE** · Cardiovascular
Source: <https://www.510kdatabase.net/k223472/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Nov 17, 2022
Decision date	Dec 15, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	TightRail Guardian Motorized Dilator Sheath, 11 French (575-011); TightRail Guardian Motorized Dilator Sheath, 13 French (575-013)

APPLICANT

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

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