

K212784 TightRail Guardian Motorized Dilator SheathAug 24, 2022
357 days to decisionK212784 · Product code: **DRE** · CardiovascularSource: <https://www.510kdatabase.net/k212784/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Sep 1, 2021
Decision date	Aug 24, 2022
Days to decision	357 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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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