

K092378 SPECTRANETICS VISISHEATH DILATOR SHEATHNov 2, 2009
89 days to decisionK092378 · Product code: **DRE** · CardiovascularSource: <https://www.510kdatabase.net/k092378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Aug 5, 2009
Decision date	Nov 2, 2009
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spectranetics Corp.
Location	Colorado Springs, CO, US
Contact	CHERYL HASTINGS
510(k) history	24 submissions · 24 cleared · 1999-2014

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