

**K043401 SPECTRANETICS LLD CS, MODEL 518-039**Mar 16, 2005  
96 days to decisionK043401 · Product code: **DRB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k043401/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stylet, Catheter (DRB)
Date received	Dec 10, 2004
Decision date	Mar 16, 2005
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Spectranetics Corp.</b>
Location	Colorado Springs, CO, US
Contact	MICHAEL J RYAN
510(k) history	24 submissions · 24 cleared · 1999-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043401/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 7, 2026