

**K133631 LEXIPLIANT DILATOR SHEATH SET**Mar 27, 2014  
121 days to decisionK133631 · Product code: **DRE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k133631/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Nov 26, 2013
Decision date	Mar 27, 2014
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spectranetics Corporation</b>
Location	Colorado Springs, CO, US
Contact	STACEY A STRAND
510(k) history	2 submissions · 2 cleared · 2014-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133631/> 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 6, 2026