

K140047 LEXICONTURE MECHANICAL DILATOR SHEATH SETApr 9, 2014
90 days to decisionK140047 · Product code: **DRE** · Cardiovascular
Source: <https://www.510kdatabase.net/k140047/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Jan 9, 2014
Decision date	Apr 9, 2014
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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