FDA 510(k) Premarket Notification

K133631 LEXIPLIANT DILATOR SHEATH SET

CLEARED

Mar 27, 2014
121 days to decision

K133631 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k133631/

SUBMISSION DETAILS

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

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