

**K161384 Lithoplasty Peripheral Balloon Dilatation Catheter,
Lithoplasty Generator and Connector Cable, Lithoplasty
Connector Cable**Sep 14, 2016
118 days to decisionK161384 · Product code: **PPN** · Cardiovascular
Source: <https://www.510kdatabase.net/k161384/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percutaneous Catheter, Ultrasound (PPN)
Date received	May 19, 2016
Decision date	Sep 14, 2016
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shockwave Medical, Inc.
Location	Fremont, CA, US
Contact	NORA HADDING
510(k) history	12 submissions · 12 cleared · 2016-2025

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