

K163306 Lithoplasty Peripheral Balloon Dilatation CatheterDec 22, 2016
29 days to decisionK163306 · Product code: **PPN** · Cardiovascular
Source: <https://www.510kdatabase.net/k163306/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Percutaneous Catheter, Ultrasound (PPN)
Date received	Nov 23, 2016
Decision date	Dec 22, 2016
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary
Other names	Lithoplasty Generator And Connector Cable; Lithoplasty Connector Cable

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163306/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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