

K191840 Peripheral Intravascular Lithotripsy (IVL) Catheters, IVL Generator and Connector Cable Kit, IVL Connector Cable (Replacement)Aug 7, 2019
29 days to decisionK191840 · Product code: **PPN** · Cardiovascular
Source: <https://www.510kdatabase.net/k191840/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Percutaneous Catheter, Ultrasound (PPN)
Date received	Jul 9, 2019
Decision date	Aug 7, 2019
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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