

K180958 Shockwave M5 Peripheral Intravascular Lithotripsy (IVL) Catheter, Intravascular Lithotripsy (IVL) Generator And Connector Cable, Intravascular Lithotripsy (IVL) Connector CableJul 26, 2018
105 days to decisionK180958 · Product code: **PPN** · Cardiovascular
Source: <https://www.510kdatabase.net/k180958/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percutaneous Catheter, Ultrasound (PPN)
Date received	Apr 12, 2018
Decision date	Jul 26, 2018
Days to decision	105 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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