

K242213 Shockwave Intravascular Lithotripsy (IVL) System with the Javelin Peripheral Intravascular Lithotripsy (IVL) CatheterSep 27, 2024
60 days to decisionK242213 · Product code: **PPN** · Cardiovascular
Source: <https://www.510kdatabase.net/k242213/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percutaneous Catheter, Ultrasound (PPN)
Date received	Jul 29, 2024
Decision date	Sep 27, 2024
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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