

K203365 Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave M5+ Peripheral IVL CatheterApr 22, 2021
157 days to decisionK203365 · Product code: **PPN** · Cardiovascular
Source: <https://www.510kdatabase.net/k203365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percutaneous Catheter, Ultrasound (PPN)
Date received	Nov 16, 2020
Decision date	Apr 22, 2021
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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