

K180454 Shockwave Medical Intravascular Lithotripsy (IVL) System

Jun 27, 2018
127 days to decision

K180454 · Product code: **PPN** · Cardiovascular
Source: <https://www.510kdatabase.net/k180454/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percutaneous Catheter, Ultrasound (PPN)
Date received	Feb 20, 2018
Decision date	Jun 27, 2018
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

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.net

Device record: <https://www.510kdatabase.net/k180454/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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