

K262201 Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave E8 Peripheral IVL Catheter

Jul 27, 2026
28 days to decision

K262201 · Product code: PPN · Cardiovascular
Source: <https://www.510kdatabase.net/k262201/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Percutaneous Catheter, Ultrasound (PPN)
Date received	Jun 29, 2026
Decision date	Jul 27, 2026
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shockwave Medical, Inc.
Location	Fremont, CA, US
Contact	Eric Fang
510(k) history	13 submissions · 13 cleared · 2016-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k262201/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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