

**K221041 Shockwave Medical Peripheral Intravascular Lithotripsy (IVL) System**Apr 25, 2022  
17 days to decisionK221041 · Product code: **PPN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k221041/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Percutaneous Catheter, Ultrasound (PPN)
Date received	Apr 8, 2022
Decision date	Apr 25, 2022
Days to decision	17 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shockwave Medical, Inc.</b>
Location	Fremont, CA, US
Contact	Soraya L Hori
510(k) history	12 submissions · 12 cleared · 2016-2025

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221041/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026