

K243757 Shockwave CS Guide CatheterMay 2, 2025
147 days to decisionK243757 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k243757/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 6, 2024
Decision date	May 2, 2025
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243757/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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