

K254278 Arterial Pressure Monitoring Set/TrayMar 25, 2026
85 days to decisionK254278 · Product code: **DQO** · CardiovascularSource: <https://www.510kdatabase.net/k254278/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Dec 30, 2025
Decision date	Mar 25, 2026
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spectrum Vascular
Location	White Plains, NY, US
Contact	Sharon Klugewicz
510(k) history	4 submissions · 4 cleared · 2024-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k254278/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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