

K241115 SV Spectrum MRC Central Venous CatheterNov 27, 2024
218 days to decisionK241115 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k241115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Apr 23, 2024
Decision date	Nov 27, 2024
Days to decision	218 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SV Spectrum MR Central Venous Catheter; SV Central Venous Catheter

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/k241115/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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