

K252677 Polyshield Safety IV CathetersNov 5, 2025
72 days to decisionK252677 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k252677/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Aug 25, 2025
Decision date	Nov 5, 2025
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Poly Medicare Limited
Location	Jaipur, IN
Contact	S. S. Rawat
510(k) history	6 submissions · 6 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	Donawa Lifescience
Contact	Roger Gray

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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