

K230616 Polyguard and Polyshield Safety IV CathetersMay 5, 2023
60 days to decisionK230616 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k230616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Mar 6, 2023
Decision date	May 5, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Donawa Lifescience Consulting Srl
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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