

K231401 Polysafety BC, Polysafety BC Adva, Polywin Safety, Polywin Safety AdvaSep 21, 2023
129 days to decisionK231401 · Product code: FOZ · General Hospital
Source: <https://www.510kdatabase.net/k231401/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	May 15, 2023
Decision date	Sep 21, 2023
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231401/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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