FDA 510(k) Premarket Notification

K252513 Polywin Safety (14G x 51mm

CLEARED

Apr 1, 2026
233 days to decision

K252513 · Product code: **FOZ** · General Hospital
Source: https://www.510kdatabase.net/k252513/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Aug 11, 2025
Decision date	Apr 1, 2026
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	16G x 51mm; 18G x 64mm; 20G x 64mm; 20G x 45mm; 22G x 64mm; 22G x 45mm; 24G x 32mm; 24G x 14mm, 26G x 14mm); Polywin Safety Adva (20G x 45mm; 22G x 64mm; 22G x 45mm ; 24G x 32 mm; 24G x 14mm; 14G x 51mm; 16G x 51mm; 18G x 64mm; 20G x 64mm, 26G x 14mm)

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Gsa2 Group, LLC**
Contact	Sunita Teekasingh

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