FDA 510(k) Premarket Notification

K232234 Nouvo Safety Set

CLEARED

Mar 15, 2024
232 days to decision

K232234 · Product code: **FOZ** · General Hospital
Source: https://www.510kdatabase.net/k232234/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Jul 27, 2023
Decision date	Mar 15, 2024
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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