FDA 510(k) Premarket Notification

K963571 VYGON MULTI-DOSE VIAL ADAPTER & BIONECTOR

CLEARED

Jun 2, 1997
270 days to decision

K963571 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k963571/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 5, 1996
Decision date	Jun 2, 1997
Days to decision	270 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Vygon Corp.**
Location	East Rutherford, NJ, US
Contact	ANNE MARIE CESARIO
510(k) history	48 submissions · 46 cleared · 1985-2012