FDA 510(k) Premarket Notification

K854547 MONOJECT STERILE M200 ALUMINUM/M250 POLYPROPYLENE

CLEARED

Feb 4, 1986
83 days to decision

K854547 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k854547/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 13, 1985
Decision date	Feb 4, 1986
Days to decision	83 days
Third-party review	No

APPLICANT

Company	**Sherwood Medical Co.**
Location	Mchenry, IL, US
Contact	FRANK J FUCILE
510(k) history	191 submissions · 177 cleared · 1976-1998