FDA 510(k) Premarket Notification

K911037 SAFETY NEEDLE SHEATH, MODIFICATION

CLEARED

May 3, 1991
63 days to decision

K911037 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k911037/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 1, 1991
Decision date	May 3, 1991
Days to decision	63 days
Third-party review	No

APPLICANT

Company	**Concord/Portex**
Location	Keene, NH, US
Contact	ROBERT WHEELER
510(k) history	23 submissions · 20 cleared · 1989-1993