FDA 510(k) Premarket Notification

K945825 SECURE SAFETY INSERT

CLEARED

Apr 10, 1995
132 days to decision

K945825 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k945825/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 29, 1994
Decision date	Apr 10, 1995
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Syncor Intl. Corp.**
Location	Mchenry, IL, US
Contact	DON REICH
510(k) history	31 submissions · 31 cleared · 1983-1995

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k945825/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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