FDA 510(k) Premarket Notification

K001965 SAFE-POINT VAC, SAFE-POINT M-D BLOOD COLLECTION SYSTEMS

CLEARED

Feb 2, 2001
219 days to decision

K001965 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k001965/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 28, 2000
Decision date	Feb 2, 2001
Days to decision	219 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**North American Medical Products, Inc.**
Location	Walker, MI, US
Contact	ARTHUR GIANAKOS
510(k) history	6 submissions · 6 cleared · 1984-2001