FDA 510(k) Premarket Notification

K964042 EXTRESAFE PHLEBOTOMY

CLEARED

Jun 6, 1997
241 days to decision

K964042 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k964042/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Oct 8, 1996
Decision date	Jun 6, 1997
Days to decision	241 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Specialized Health Products, Inc.**
Location	Bountiful, UT, US
Contact	WILLIAM E MCKAY
510(k) history	4 submissions · 4 cleared · 1996-2005