FDA 510(k) Premarket Notification

K970800 MAXCESS NEEDLEFREE - Y- SITE (100713)

CLEARED

Apr 2, 1997
29 days to decision

K970800 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k970800/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Mar 4, 1997
Decision date	Apr 2, 1997
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Solopak Medical Products, Inc.**
Location	Libertyville, IL, US
Contact	ELIZABETH LOYA
510(k) history	4 submissions · 4 cleared · 1996-1997