FDA 510(k) Premarket Notification

K001599 ACTI-FLEX IV ADMINISTRATION SET

CLEARED

Sep 18, 2000
117 days to decision

K001599 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k001599/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	May 24, 2000
Decision date	Sep 18, 2000
Days to decision	117 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**R-Group Intl.**
Location	Gainesville, FL, US
Contact	KERRY ANNE KAHN
510(k) history	7 submissions · 7 cleared · 1992-2000