FDA 510(k) Premarket Notification

K972839 PROTOS 100ML BURETTE INFUSION SET/ PROTOS 150ML BURETTE INFUSION SET

CLEARED

Dec 17, 1997
138 days to decision

K972839 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k972839/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Aug 1, 1997
Decision date	Dec 17, 1997
Days to decision	138 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Globe Ent., Inc.**
Location	Houston, TX, US
Contact	STEPHEN Y JAN
510(k) history	5 submissions · 5 cleared · 1989-1997