

**K972854 PROTOS I.V. ADMINISTRATION SET (15 DROPS/ML)
I4070S/(60 DROPS/ML)I4670S PRELIMINARY**

Dec 17, 1997
138 days to decision

K972854 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k972854/>

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k972854/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026