FDA 510(k) Premarket Notification

K914113 ANGIOGRAPHIC FLUSH SYSTEM

CLEARED

Jan 22, 1992
131 days to decision

K914113 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k914113/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 13, 1991
Decision date	Jan 22, 1992
Days to decision	131 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**E-Z-Em, Inc.**
Location	Mchenry, IL, US
Contact	MERRIBETH ADAMS
510(k) history	56 submissions · 56 cleared · 1977-2007