FDA 510(k) Premarket Notification

K011336 PRIMARY SOLUTION SET WITH UNIVERSAL SPIKE, INJECTION SITE AND MALE LUER LOCK

CLEARED

Jun 12, 2001
41 days to decision

K011336 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k011336/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	May 2, 2001
Decision date	Jun 12, 2001
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Churchill Medical Systems, Inc.**
Location	Horsham, PA, US
Contact	KEITH PAULCH
510(k) history	12 submissions · 12 cleared · 1988-2004