

**K011336 PRIMARY SOLUTION SET WITH UNIVERSAL SPIKE,
INJECTION SITE AND MALE LUER LOCK**Jun 12, 2001
41 days to decisionK011336 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011336/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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