

K953474 IV START KITOct 2, 1995
70 days to decisionK953474 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k953474/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jul 24, 1995
Decision date	Oct 2, 1995
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medikmark, Inc.
Location	Chicago, IL, US
510(k) history	8 submissions · 4 cleared · 1992-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953474/>; 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 May 26, 2026