

K003513 TAXOL ADMINISTRATION SETJan 11, 2001
58 days to decisionK003513 · Product code: **FPA** · General HospitalSource: <https://www.510kdatabase.net/k003513/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Nov 14, 2000
Decision date	Jan 11, 2001
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Icu Medical, Inc.
Location	Walker, MI, US
Contact	SALVADORE F PALOMARES
510(k) history	66 submissions · 65 cleared · 1984-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003513/> 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 28, 2026