

K961513 PROCATH LOCKING PEEL-AWAY INTRODUCER/PEEL-AWAY INTRODUCER SETMay 13, 1996
24 days to decisionK961513 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k961513/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 19, 1996
Decision date	May 13, 1996
Days to decision	24 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ep Medsystems
Location	West Berlin, NJ, US
Contact	JOSEPH C GRIFFIN
510(k) history	12 submissions · 12 cleared · 1996-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961513/> 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 18, 2026