FDA 510(k) Premarket Notification

K881825 MODELS SP5825/SP5835/SP5845/SP5855 PERCU. SHEATH

CLEARED

Sep 28, 1988
152 days to decision

K881825 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k881825/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 29, 1988
Decision date	Sep 28, 1988
Days to decision	152 days
Third-party review	No

APPLICANT

Company	**Spectramed, Inc.**
Location	Findley, MN, US
Contact	ROBERT L LEAVITT
510(k) history	13 submissions · 13 cleared · 1987-1990