FDA 510(k) Premarket Notification

K892941 CCO SYSTEM MODEL SP1467,SP5567,SP6267

CLEARED

Nov 6, 1989
199 days to decision

K892941 · Product code: **KRB** · Cardiovascular
Source: https://www.510kdatabase.net/k892941/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Probe, Thermodilution (KRB)
Date received	Apr 21, 1989
Decision date	Nov 6, 1989
Days to decision	199 days
Third-party review	No

APPLICANT

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