FDA 510(k) Premarket Notification

K864818 ACKRAD TDI SET

CLEARED

Apr 9, 1987
121 days to decision

K864818 · Product code: **KRB** · Cardiovascular
Source: https://www.510kdatabase.net/k864818/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Probe, Thermodilution (KRB)
Date received	Dec 9, 1986
Decision date	Apr 9, 1987
Days to decision	121 days
Third-party review	No

APPLICANT

Company	**Ackrad Laboratories**
Location	Mchenry, IL, US
Contact	BERNARD ACKERMAN
510(k) history	42 submissions · 41 cleared · 1979-2002