FDA 510(k) Premarket Notification

K892368 RMI CARDIOPLEGIA DELIVERY SETS

CLEARED

Dec 7, 1989
245 days to decision

K892368 · Product code: **DTL** · Cardiovascular
Source: https://www.510kdatabase.net/k892368/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Apr 6, 1989
Decision date	Dec 7, 1989
Days to decision	245 days
Third-party review	No

APPLICANT

Company	**Research Medical, Inc.**
Location	Mchenry, IL, US
Contact	MICHAEL N KELLY
510(k) history	35 submissions · 35 cleared · 1984-1997