FDA 510(k) Premarket Notification

K897137 RMI AORTIC ROOT/CORONARY SINUS PRESSURE MONITORING

CLEARED

Mar 27, 1990
90 days to decision

K897137 · Product code: **DTL** · Cardiovascular
Source: https://www.510kdatabase.net/k897137/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Dec 27, 1989
Decision date	Mar 27, 1990
Days to decision	90 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