FDA 510(k) Premarket Notification

K861790 RMI BALLOON-OCCLUSIVE CAROTID BY-PASS SHUNT

CLEARED

Jul 21, 1986
73 days to decision

K861790 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k861790/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	May 9, 1986
Decision date	Jul 21, 1986
Days to decision	73 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