FDA 510(k) Premarket Notification

K883412 THE CARPENTIER TRANS-MITRAL VENTRICULAR VENT(TM)

CLEARED

Feb 8, 1989
177 days to decision

K883412 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k883412/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Aug 15, 1988
Decision date	Feb 8, 1989
Days to decision	177 days
Third-party review	No

APPLICANT

Company	**Promedica Products, Inc.**
Location	Newport Beach, CA, US
Contact	LEE HAND
510(k) history	6 submissions · 6 cleared · 1988-1992