FDA 510(k) Premarket Notification

K781990 CARDIAC INSULATION PAD

CLEARED

Dec 4, 1978
7 days to decision

K781990 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k781990/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Nov 27, 1978
Decision date	Dec 4, 1978
Days to decision	7 days
Third-party review	No

APPLICANT

Company	**Shiley, Inc.**
Location	Mchenry, IL, US
510(k) history	174 submissions · 174 cleared · 1976-1993