FDA 510(k) Premarket Notification

K872722 EXPANDED USE FOR SHILEY 3L CARDF PLUS

CLEARED

Sep 23, 1987
75 days to decision

K872722 · Product code: **DTN** · Cardiovascular
Source: https://www.510kdatabase.net/k872722/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Jul 10, 1987
Decision date	Sep 23, 1987
Days to decision	75 days
Third-party review	No

APPLICANT

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