FDA 510(k) Premarket Notification

K823731 CARDF

CLEARED

Jan 5, 1983
26 days to decision

K823731 · Product code: **DTP** · Cardiovascular
Source: https://www.510kdatabase.net/k823731/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Defoamer, Cardiopulmonary Bypass (DTP)
Date received	Dec 10, 1982
Decision date	Jan 5, 1983
Days to decision	26 days
Third-party review	No

APPLICANT

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