FDA 510(k) Premarket Notification

K833830 3-DAY BIOINDICATOR RELEASE PROCESS FOR

CLEARED

Apr 12, 1984
157 days to decision

K833830 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k833830/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Nov 7, 1983
Decision date	Apr 12, 1984
Days to decision	157 days
Third-party review	No

APPLICANT

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