FDA 510(k) Premarket Notification

K991783 AB-180 XC SYSTEM, MODEL AB-180XC

CLEARED

Nov 1, 2000
526 days to decision

K991783 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k991783/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	May 25, 1999
Decision date	Nov 1, 2000
Days to decision	526 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiacassist, Inc.**
Location	Pittsburgh, PA, US
Contact	RICHARD G CONFER
510(k) history	21 submissions · 21 cleared · 2000-2024