FDA 510(k) Premarket Notification

K110493 TANDEMHEART PUMP

CLEARED

Sep 20, 2011
210 days to decision

K110493 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k110493/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Feb 22, 2011
Decision date	Sep 20, 2011
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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