FDA 510(k) Premarket Notification

K111384 LIFEBRIDGE

CLEARED

May 24, 2011
7 days to decision

K111384 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k111384/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	May 17, 2011
Decision date	May 24, 2011
Days to decision	7 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lifebridge Medizintechnik AG**
Location	Bryn Mawr, PA, US
Contact	KATHLEEN JOHNSON
510(k) history	3 submissions · 3 cleared · 2009-2011