FDA 510(k) Premarket Notification

CLEARED

K090515 ROTAFLOW CENTRIFUGAL PUMP WITH SOFTLINE COATING, MODEL BO-RF-32 (USA)

Dec 18, 2009
295 days to decision

K090515 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k090515/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Feb 26, 2009
Decision date	Dec 18, 2009
Days to decision	295 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Maquet Cardiopulmonary, AG**
Location	Fairfield, IA, US
Contact	FRANK MOEHRKE
510(k) history	44 submissions · 44 cleared · 2005-2015