FDA 510(k) Premarket Notification

K051209 LEVITRONIX CENTRIMAG BACK-UP CONSOLE

CLEARED

Sep 8, 2005
120 days to decision

K051209 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k051209/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	May 11, 2005
Decision date	Sep 8, 2005
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Levitronix, LLC**
Location	Waltham, MA, US
Contact	FARZAD PARSAIE
510(k) history	11 submissions · 11 cleared · 2003-2011