FDA 510(k) Premarket Notification

CLEARED

K053630 LEVITRONIX CENTRIMAG PRIMARY CONSOLE

Jan 26, 2006
28 days to decision

K053630 · Product code: **DWA** · Cardiovascular
Source: https://www.510kdatabase.net/k053630/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Control, Pump Speed, Cardiopulmonary Bypass (DWA)
Date received	Dec 29, 2005
Decision date	Jan 26, 2006
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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