FDA 510(k) Premarket Notification

K081221 LEVITRONIX CENTRIMAG PRIMARY CONSOLE, THORATEC CENTRIMAG PRIMARY CONSOLE

CLEARED

Jun 19, 2008
50 days to decision

K081221 · Product code: **DWA** · Cardiovascular
Source: https://www.510kdatabase.net/k081221/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Pump Speed, Cardiopulmonary Bypass (DWA)
Date received	Apr 30, 2008
Decision date	Jun 19, 2008
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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