FDA 510(k) Premarket Notification

K083340 LEVITRONIX CENTRIMAG PRIMARY CONSOLE

CLEARED

Nov 26, 2008
14 days to decision

K083340 · Product code: **DWA** · Cardiovascular
Source: https://www.510kdatabase.net/k083340/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Control, Pump Speed, Cardiopulmonary Bypass (DWA)
Date received	Nov 12, 2008
Decision date	Nov 26, 2008
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary
Other names	THORATEC CANTRIMAG PRIMARY CONSOLE

APPLICANT

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