FDA 510(k) Premarket Notification

K090004 LEVITRONIX, THORATEC CENTRIMAG BACK-UP CONSOLES

CLEARED

Jan 15, 2009
13 days to decision

K090004 · Product code: **DWA** · Cardiovascular
Source: https://www.510kdatabase.net/k090004/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Control, Pump Speed, Cardiopulmonary Bypass (DWA)
Date received	Jan 2, 2009
Decision date	Jan 15, 2009
Days to decision	13 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