

**K090004 LEVITRONIX, THORATEC CENTRIMAG BACK-UP
CONSOLES**Jan 15, 2009
13 days to decisionK090004 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090004/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026