FDA 510(k) Premarket Notification

K102129 LEVITRONIX 2ND GENERATION CENTRIMAG PRIMARY CONSOLE, LEVITRONIX MONITOR

CLEARED

Aug 27, 2010
29 days to decision

K102129 · Product code: **DWA** · Cardiovascular
Source: https://www.510kdatabase.net/k102129/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Control, Pump Speed, Cardiopulmonary Bypass (DWA)
Date received	Jul 29, 2010
Decision date	Aug 27, 2010
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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