FDA 510(k) Premarket Notification

CLEARED

K020271 LEVITRONIX CENTRIMAG EXTRACORPOREAL BLOOD PUMPING SYSTEM, MODEL L-100

Mar 25, 2003
421 days to decision

K020271 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k020271/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Jan 28, 2002
Decision date	Mar 25, 2003
Days to decision	421 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