K102129

AUG 27 2010

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92.

A. Application Information

Date Prepared:	July 28, 2010
Submitter's Name & Address:	Levitronix LLC 45 First Avenue Waltham, MA 02451
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B. Device Information

Trade or Proprietary Name:	1. Levitronix 2nd Generation CentriMag® Primary Console 2. Levitronix Monitor
Common or Usual Name:	Cardiopulmonary Bypass Pump Console
Classification Name:	Class II, DWA, 21 CFR – 870.4380 Control, Pump Speed, Cardiopulmonary Bypass
Performance Standard:	Performance standards do not currently exist for these devices. None established under section 514 of the Food, Drug and Cosmetic Act.

C. Legally Marketed Predicate Devices

- Levitronix CentriMag System (K020271)
- Levitronix CentriMag Primary Console (K083340)

D. Device Description

- **2nd Generation CentriMag Primary Console**

The 2nd Generation CentriMag Primary Console is a microprocessor based device. The microprocessor generates the primary motor control signal, monitors system sensors, generates display outputs, interprets the inputs through the front keypad, provides alarm functions and handles the Levitronix Monitor interface. The Console is intended to be operated on single phase AC power; however, it also has a built-in rechargeable battery with a battery charger. The rechargeable battery is field replaceable. In addition, an optional external modular battery (UPS) can be used to power the CentriMag Primary Console. The human interface of the CentriMag Primary Console consists of a graphical screen to display data and system options and touch pads to change the system status. The 2nd Generation CentriMag Primary Console is intended to be used together with the Levitronix Monitor; however it can be also operated as a stand-alone unit.

- **Levitronix Monitor**

The Levitronix Monitor provides a redundant user interface containing a display and touch pads. The Primary and Back-Up Consoles also provide a fully-functional user interface containing a display and touch pads. The Levitronix Monitor is a non-sterile, reusable device that is designed to work only with the 2nd Generation CentriMag Primary Console; therefore, it does not support the 1st Generation CentriMag Primary Console or the CentriMag Back-Up Console. The Levitronix Monitor is a 12V DC-powered device and receives its power directly from 2nd Generation CentriMag Primary Console via a power connector that mates with a connector on the back-panel of 2nd Generation CentriMag Primary Console. Based on the design of its power connector, the Levitronix Monitor cannot be plugged into a hospital AC power outlet. The Levitronix Monitor's core function is to provide multi-color alpha-numerical and graphical displays of information it receives from the 2nd Generation CentriMag Primary Console. The Levitronix Monitor is intended for use as a hospital-based unit (OR and bed-side) and is not intended for use during patient transport from one hospital to another.

The Levitronix Monitor is a processor based device, with a flat color screen (e.g. LCD). In addition, it is equipped with touch pad to allow the user to enter commands. In the hospital-setting configuration, the user is able to operate and monitor the performance of the CentriMag System through the Levitronix Monitor. The Levitronix Monitor can control the functions of the 2nd Generation CentriMag Primary Console, and therefore, of the CentriMag System. The Levitronix Monitor only displays data and stores user commands without interacting directly with the primary motor control which is managed by the 2nd Generation CentriMag Primary Console. The Levitronix Monitor is connected to the 2nd Generation CentriMag Primary Console through one cable, which includes data and power lines. Power is provided by the 2nd Generation CentriMag Primary Console.

E. Intended Use

The Levitronix 2nd Generation CentriMag Primary Console and Levitronix Monitor are indicated for use with the Levitronix CentriMag Extracorporeal Blood Pumping System. The Levitronix CentriMag Extracorporeal Blood Pumping System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc).

F. Technological Characteristics

The technological characteristics of the Levitronix 2nd Generation CentriMag Primary Console and the Levitronix Monitor are the same as the predicate devices.

G. Comparison to Predicate Device

The Levitronix 2nd Generation CentriMag Primary Console and the Levitronix Monitor have an indication for use, design features, and functional characteristics which are substantially equivalent to the predicate devices. Due to the equivalency of indications for use, design features, and functional characteristics, these devices raise no new safety or effectiveness issues.

H. Summary of Performance Data

The Levitronix 2nd Generation CentriMag Primary Console and the Levitronix Monitor have successfully undergone functional testing demonstrating substantial equivalence to the predicate devices.

The risk management methods used to assess the operational integrity of the 2nd Generation CentriMag Primary Console and the Levitronix Monitor were a Risk Analysis and a Failure Modes and Effects Analysis (FMEA).

I. Clinical Performance

Clinical testing was not performed. The 2nd Generation Console and Levitronix Monitor were CE Mark approved on February 5, 2010 and have been successfully used clinically in Europe in the commercial market.

J. Conclusion

The Levitronix 2nd Generation CentriMag Primary Console and the Levitronix Monitor are substantially equivalent to the Levitronix CentriMag Primary Console (K083340) and the Levitronix CentriMag System (K020271).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Levitronix LLC
c/o Mr. Farzad Parsaie
VP Regulatory Affairs/Quality Assurance
45 First Avenue
Waltham, MA 02451

AUG 27 2010

Re: K102129
Levitronix 2nd Generation CentriMag Primary Console, Levitronix Monitor
Regulation Number: 21 CFR 870.4380
Regulation Name: Control, Pump Speed, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DWA
Dated: July 28, 2010
Received: July 29, 2010

Dear Mr. Parsaie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102129

Indications for Use Statement

Applicant: **Levitronix LLC**

510(k) Number (if known): K102129

Device Name: **CentriMag® 2nd Generation Primary Console & Levitronix® Monitor**

Indications for Use:

The Levitronix 2nd Generation CentriMag Primary Console and Levitronix Monitor are indicated for use with the Levitronix CentriMag Extracorporeal Blood Pumping System. The Levitronix CentriMag Extracorporeal Blood Pumping System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc).

Prescription Use ____✓____ OR Over-the Counter Use _____
(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K102129

(Optional Format 1-2-96)