MAR 2 5 2003

Summary of Safety & Effectiveness

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 15, 2002
Submitter's Name & Address:	Levitronix, LLC 85 First Avenue Waltham, MA 02451
Contact Person:	Farzad Parsaie V.P., RA/QA Ph: (781) 622-5075 Fax: (781) 622-5090 e-mail: fparsaie@pharosllc.com

B. Device Information:

Trade or Proprietary Name:	Levitronix CentriMag® Extracorporeal Blood Pumping System
Common or Usual Name:	Centrifugal Blood Pump Cardiopulmonary Bypass Pump Console
Classification Name(s):	Class III, KFM, 21 CFR - 870.4360 Pump, Blood, Cardiopulmonary Bypass, Non-roller type Class II, DWA, 21 CFR – 870.4380 Control, Pump Speed, Cardiopulmonary Bypass ***Note: Non-roller type blood pumps have been classified as Class III devices by the Cardiovascular Devices Panel (Product Code 74KFM). A petition for reclassification of this type of device from Class III to Class II has been approved by the panel, but the final rule has not been promulgated yet.***

Performance Standard:	Performance standards do not currently exist for these devices. None established under section 514 of the Food, Drug and Cosmetic Act.

C. Predicate Devices:

The Levitronix CentriMag® Extracorporeal Blood Pumping System is believed to be substantially equivalent to the following predicate devices currently in interstate commerce with respect to comparable features, materials of construction and intended use:

Predicate Device - Centrifugal Blood Pump		
Device Name	**Manufacturer**	**510(k) No.**
Bio-Pump, Model BPX-80	Medtronic	K973011

Predicate Device - Blood Pump Speed Controller		
Device Name	**Manufacturer**	**510(k) No.**
Bio-Console, Model 550	Medtronic	K941921

D. Device Description

System - The Levitronix CentriMag® Extracorporeal Blood Pumping System is a fault-tolerant system comprised of four (4) main assemblies which are available separately:

- Blood Pump
- Remote Motor Drive Unit
- Control Console
- Ultrasonic Flow Sensor

Blood Pump - The Levitronix CentriMag® Extracorporeal Blood Pump is a sterile, single-use, disposable, non-pulsatile, non-roller pump that utilizes a rotor to impart energy to the blood in an extracorporeal circuit through centrifugal forces. The inlet to the pump runs concentric with the axis of the rotor. The outlet of the pump is perpendicular to the inlet and tangent to the outer diameter. Blood enters the pump housing via the pump's inlet port where it makes contact with the rotor. As the rotor turns, energy in the form of pressure and velocity is transferred from the rotor to the blood. The CentriMag® Extracorporeal Blood Pump moves the blood through the circuit at a desired pressure and flow rate by increasing or decreasing the speed of the rotor. This is accomplished by adjusting the CentriMag® Console's RPM (revolutions per minute).

The pump operates from the Levitronix Remote Motor Drive Unit and microprocessor-based console, located outside the sterile field.

Remote Motor Drive Unit – The CentriMag® Motor Drive Unit is positionable on an IV pole/mast or adjacent to the console using an optional utility post. The Motor Drive Unit holds the disposable blood pump and drives the rotor inside the blood pump.

Control Console - The Levitronix CentriMag® Console is a microprocessor-based device, which drives and controls the speed of the blood pump in the extracorporeal circuit. The console also provides monitoring of motor speed, fluid flow, and pressure through the use of alphanumeric display, audible alarms and visible alarms.

Ultrasonic Flow Sensor – The Levitronix CentriMag® Extracorporeal Blood Pumping System includes an ultrasonic flow meter.

E. Intended Use

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 Levitronix CentriMag® Extracorporeal Blood Pumping System has technological characteristics similar to the predicate devices.

Blood Pump – The Levitronix CentriMag® Extracorporeal Blood Pump consists of injection-molded polycarbonate inner and outer housings containing an injection-molded polycarbonate rotor, which imparts energy to the pumping fluid through centrifugal forces. The joints are bonded with an ultraviolet light cured adhesive. The inlet port (3/8") is located at the top center of the pump and the fluid inflow runs concentric with the axis of the rotor. The outlet port (3/8") of the pump is perpendicular to the inlet and tangent to the outer diameter. The rotor contains a magnet that is hermetically sealed. The Levitronix CentriMag® Extracorporeal Blood Pump is designed to be used only with Levitronix CentriMag® Console.

An ultrasonic flow meter is provided to monitor the pump output. Optional pressure transducers are available to monitor inlet/outlet pressures.

Remote Motor Drive Unit – The Motor Drive Unit turns a magnet that is hermetically sealed in the pump's rotor at a speed that is set by the console operator. Three bayonet sockets are provided on the top of the Motor allowing coupling and mounting of the disposable blood pump in three angular directions (90 degrees apart) of the pump outlet. An array of hall sensors in the motor is used to determine motor speed.

Control Console – The Levitronix CentriMag® Console is a microprocessor-based device. The microprocessor generates the primary motor control signal, monitors system sensors, generates front display outputs, and provides alarm functions. The microprocessor acquires the sensor data for use in generating operator displays and alarms. An alphanumeric screen is used to display monitored data, system options, and menus. Operator settable alarms and parameters are accessible via the system menus.

The CentriMag® console operates off of single phase AC power and is capable of flow rate of up to 9.99 LPM against a maximum pressure head of 600 mmHg. In addition each console contains an internal battery that is capable of running the pump for a minimum of 60 minutes when fully charged at maximum speed of 5,500 and under nominal load in the event of a loss of AC Power.

Ultrasonic Flow Sensor – The Flow Sensor is a reusable, non-patient contacting ultrasonic flow sensor which can detect flows from 0-9.99 LPM and can detect retrograde flow of $\geq$40 cc/min. This sensor is compatible with 3/8" ID by 3/32" wall tubing.

G. Comparison to Predicate Devices

The Levitronix CentriMag® Extracorporeal Blood Pumping System has indications for use which are substantially equivalent to those of predicate devices, is composed of the same or equivalent materials as the commercially marketed devices, has equivalent design features as the predicate devices, and has functional characteristics which are the same or equivalent to those of the predicate devices. Due to the equivalency of indications for use, materials of composition, design features, and functional characteristics, the device raises no new safety or effectiveness issues.

H. Summary of Performance Data

The performance characteristics of the Levitronix CentriMag® Extracorporeal Blood Pumping System were tested and compared with Levitronix performance specifications established for the system and with commercially available predicate devices.

1) Iv-vivo Animal Studies

In-vivo testing was not performed on this system.

2) In-vitro Bench Testing:

In-Vitro bench testing demonstrates that when compared to the predicate devices (BPX-80 Bio-Pump), the Levitronix CentriMag® Extracorporeal Blood Pump does not significantly affect safety and effectiveness and is substantially equivalent to other commercially distributed centrifugal blood pumps.

3) **Software**

Software on-board the CentriMag® Console was validated and verified in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

4) **Biocompatibility:**

Biocompatibility testing of Levitronix CentriMag® Extracorporeal Blood Pump was performed in accordance with the FDA Blue Book Memorandum - #G95-1 and Biological Evaluation of Medical Devices Guidance – International Standard ISO 10993-1, and in accordance with United States Pharmacopoeia – XXIII.

Based on the results of the biocompatibility testing performed, the Levitronix CentriMag® Extracorporeal Blood Pump was determined to be biocompatible and non-toxic and, therefore, safe for its intended use.

5) **Sterilization:**

Sterilization of the Levitronix CentriMag® Extracorporeal Blood Pump has been validated to assure a sterility assurance level (SAL) of 10^{-6}. EtO sterilized CentriMag® Extracorporeal Blood Pumps are sterilized in accordance with the American National Standards Institute, Inc. (ANSI) standard ANSI/AAMI/ISO 11135-1994 (Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization).

6) **EtO Residuals:**

EtO dissipation curves are used for routine product release to assure EtO sterilized CentriMag® Extracorporeal Blood Pumps meet the limits for residual concentrations of ethylene oxide (<25ppm), ethylene chlorohydrin (<25ppm), and ethylene glycol (<250ppm) as published in ANSI standard Number ANSI/AAMI/ISO 10993-7 (Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals).

7) **Pyrogens:**

Routine Pyrogen Testing is performed using the Limulus Amebocyte Lysate (LAL) method. Product testing and release criteria (less than .5 EU/ml) is in accordance to the December 1987 Guideline issued by the Food and Drug Administration, Office of Compliance ("Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices").

I. **Clinical Performance**

Clinical testing was not performed on this system.

J. Conclusion & Statement of Equivalence

Through data and information presented, numerous similarities support a determination of substantial equivalence, and subsequently market clearance of the Levitronix CentriMag® Extracorporeal Blood Pumping System through this 510(k) Premarket Submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 5 2003

Levitronix, LLC
c/o Mr. Farzad Parsaie
85 First Avenue
Waltham, MA 02451

Re: K020271
CentriMag® Extracorporeal Blood Pumping System
Regulation Number: 21 CFR 870.4360
Regulation Name: Non-roller type CPB Blood Pump
Regulatory Class: Class III (three)
Product Code: KFM
Dated: December 31, 2002
Received: January 6, 2003

Dear Mr. Parsaie:

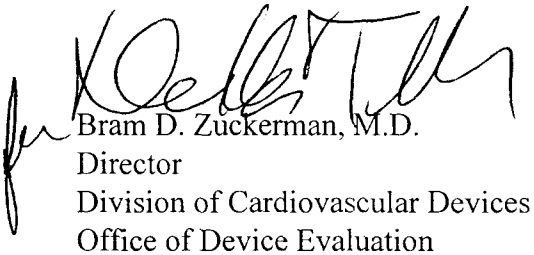
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

III. Indications For Use Statement

Applicant: **Levitronix, LLC**

510(k) Number (if known): K02027/

Device Name: **CentriMag® Extracorporeal Blood Pumping System**

Indications for Use:

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).

(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 K02027/

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

(Optional Format 1-2-96)