FEB 6 1998

K972740

18 510(K) SUMMARY OR STATEMENT

SUBMITTER: International Medical Products Corporation
4503 Moorland Avenue
Minneapolis, Minnesota 55424

Contact: Jeffery R. Shideman, Ph.D.
President

DATE PREPARED: 20 May 1997

PROPRIETARY NAME: HIMEX Centriflow ™

CLASSIFICATION NAME: Extracorporeal Centrifugal Blood Pump

Device Description:
The HIMEX Centriflow ™ is a speed controlled motor device for operating a Nikkiso HMS-12 (FDA 510(k) # K920077) disposable centrifugal pump head. The motor turns a driver magnet at a speed that is set by the device operator. The Driver Magnet magnetically couples to a magnet inside the Nikkiso HMS-12 disposable pump module. Rotation of the Driver Magnet thereby causes the impeller inside the Nikkiso HMS-12 to turn. The device also provides monitoring of motor speed, fluid flow, temperature and pressure through the use of numeric displays, graphical displays, audible alarms and visible alarms.

Predicate Devices:
Nikkiso NK Pump – K920077

Intended Use:
The HIMEX Centriflow™ Console and Remote Drive Module, when used with a Nikkiso HMS-12 disposable pump module, is a centrifugal blood pump that is intended for use in cardiopulmonary bypass procedures less than 6 hours in duration.

Technological Characteristics:
The HIMEX Centriflow™ is a modular device consisting of a console and a Remote Driver Module. A dual microprocessor configuration is used to control and monitor the speed of a brushless DC motor. The primary microprocessor, located in the console, generates the primary motor control signal, monitors system sensors, generates front display outputs, and provides alarm functions. The secondary microprocessor, located in the Remote Driver Module with the motor, generates the backup motor control signal, tracks motor usage, and displays motor speed. In the event of an error in the primary microprocessor control signal the secondary microprocessor will take control of the motor and lockout the primary microprocessor. Manual override is also provided to allow the operator to take direct control by overriding both microprocessors.

An array of hall sensors in the motor are used to determine motor speed. An ultrasonic flow meter is provided to monitor the pump output. A strain gauge air pressure transducer is provided to monitor outlet pressure. A connection is provided to accommodate a temperature probe to monitor temperature. The primary microprocessor acquires the sensor data for use in generating operator displays and alarms. Self illuminating numeric readouts are used to display monitored data. A liquid crystal graphics screen is used to display system options, menus. Operator setable alarms and parameters are accessible via the system menus. Two accessory digital timers are also provided.

Summary Of Non-Clinical Tests:
Non-Clinical testing was performed at the Baylor College of Medicine Department of Surgery. The objective of these tests were to verify that the HIMEX Centriflow™ had equivalent performance to the predicate Nikkiso NK Pump (510(k)# K920077). Both the Nikkiso NK and HIMEX Centriflow™ were subjected to a series of tests consisting of comparative performance, accuracy, and hemolysis studies using calf blood. Analysis of the raw data provided evidence that the HIMEX device was of equivalent performance to the Nikkiso device.

Clinical Test Results:
Clinical testing was not performed. Clinical test data from the Nikkiso device is applicable to the HIMEX device since the HIMEX device drives the same disposable pump head as the Nikkiso device.

Conclusion:
Testing performed on the HIMEX Centriflow™ device indicates that it is safe, effective, and performs as well as the predicate device, when used in accordance with the instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

FEB 6 1998

Mr. Greg Georges
President
HIMEX Production Corporation
1709 Dryden Road, Suite 1508
Houston, TX 77030

Re: K972740
HIMEX Centriflow™ Centrifugal Perfusion Pump
Regulatory Class: III (three)
Product Code: 74 KFM
Dated: November 14, 1997
Received: November 17, 1997

Dear Mr. Georges:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

870.4360 - KFM III - Non Roller Type CPB Blood Pump

Page____of____

510(k) Number (if known): K972740

Device Name: Centriflow Centrifugal Perfusion Pump System

Indications For Use:

The HIMEX Centriflow System is indicated for use in the maintenance of vital circulatory support as an extracorporeal circuit that is intended for use in cardiopulmonary bypass procedures less than six hours in duration.

(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, Respiratory, and Neurological Devices
510(k) Number K972740

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)