K963703

510(k) SUMMARY

Accuflo™ Electromagnetic Flow Monitoring System

The Accuflo™ Electromagnetic Flow Monitoring System is composed of three (3) components, a monitor display unit, a transducer and a sterile flow-through probe. The system is substantially equivalent to the Biomedicus Bioprobe Electromagnetic Flow System which is marketed by Medtronic, Inc.

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TABLE OF COMPARISON:

CHARACTERISTIC	ACCUFLO™ SYSTEM	BIOPROBE SYSTEM
Components	3	3
Separate Monitor	Yes	Yes
Digital Display	Yes	Yes
Zero Offset Control	Yes	Yes
Electromagnetic Transducer	Yes	Yes
Electromagnets	2	1
Disposable Flow Probe	Yes	Yes
Construction	Insert Injection Molded	Insert Injection Molded
Electrodes	3 in a row	3 pairs in a row
Inside Diameter	3/8"	3/8"
Material	Polycarbonate	Polycarbonate
Sterilization	Ethylene Oxide	Ethylene Oxide
Accuracy	Accurate within 50 ml	Accurate within 300 ml

DISCUSSION OF SIMILARITIES AND DIFFERENCES:

The use of a single electromagnet in the Bioprobe System compromises the uniformity of field within the flow-through cell. To compensate for this, two pair of electrodes are used to pick up the signal on opposite sides of the probe wall. The use of two electromagnets in the Accuflo™ System enhances the uniformity of the field within the probe so that a single electrode pair can be used to pick up the signal with improved accuracy. The Biomedicus Bioprobe System is sold as an integral part of the Biomedicus Pump Console. The Accuflo™ System is a free standing system permitting expanded utilization of this more accurate flow measurement in non centrifugal, i.e., Roller Pump, pump systems. All remaining differences are cosmetic only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

H. David Shockley, Jr.
President
Official Correspondent
International Biophysics Corporation
4020 S. Industrial Drive, Suite 160
Austin, TX 78744

APR - 8 1998

Re: K963703
Accuflo™ Electromagnetic Flow Monitoring System
Regulatory Class: II (Two)
Product Code: DPT
Dated: January 8, 1998
Received: January 12, 1998

Dear Mr. Shockley:

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

510(k) Number (if known): K963703

Device Name: Accuflo Monitoring System

Indications For Use:

INTENDED USE

The Accuflo™ Electromagnetic Flow System is intended for use in the monitoring of the extracorporeal cardiopulmonary bypass circuit blood flow rate during open heart surgery. The device will function in circuits utilizing centrifugal pump heads as well as circuits utilizing roller pumps. There are no other intended uses for the device. The equivalent device, the Bioprobe, is primarily used with centrifugal pumps.

(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 K963703

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)