DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 18 1997

Steve Boeh
Director, Quality Assurance and Regulatory Affairs
Diametrics Medical, Inc.
2658 Patton Road
Saint Paul, Minneapolis 55113

Re: K974396
Diametrics Medical IRMA Blood Analysis System
Regulatory Class: II
Product Code: CHL, CGA
Dated: November 17, 1997
Received: November 21, 1997

Dear Mr. Boeh:

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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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) 594-4588. 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K974396
Device Name: IRMA Blood Analysis System with Optional Lifescan SureStep®Pro Blood Glucose Module

Statement of Intended Use

The IRMA® Blood Analysis System is intended for professional use in those settings where direct measurement of blood such as blood gases (pCO_2 and pO_2), pH, Na+, K+, iCa++ and Hct in whole blood are performed such as the clinical laboratory or patient bedside.

and

The IRMA/Lifescan SureStep®Pro glucose module is intended for quantitative measurement of glucose in a sample of whole blood. It can be used in a clinical setting to measure glucose in arterial, venous, and capillary samples in both adults and neonates. It can also be used by lay persons for capillary blood glucose monitoring in the home.

Indications for Use:
The pH, pCO_2, pO_2 measurements, and their associated calculated values are used to assess acid-base status and state of oxygenation. Common causes of acid-base disturbances include cardiopulmonary disease, metabolic abnormalities, drugs and poisons, and fluid imbalance.

The electrolyte measurements (Na^{+}, K^{+})are used to assess hydrational status, aid in the diagnosis of respiratory and metabolic acid-balance, and prevention of cardiac arrhythmia. Common disease states which utilize these measurements are acid-base disturbances, dehydration, diarrhea, ketoacidosis, alcoholism and other toxicities.

The measurement of ionized calcium is used to assess disease states such as thyroid abnormalities, renal failure or transplant, and to monitor dialysis patients.

The measurement of hematocrit is used to assess anemia, blood loss such as in an accident or during surgical procedures, and polycythemia.

The measurement of glucose on the module is used to monitor glucose levels in diabetic patients. It is not intended to be used for the diagnosis of diabetes.

These indications for use are identical to the predicate devices since the new system consists of an integration of the two predicate devices.

U Michaels for Alfred W. Montgomery
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974396

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional F...