DIAMETRICS MEDICAL

2658 Patton Road Saint Paul MN 55113-1136 USA Phone: 651/639.8035 Fax: 651/639.8549

JUN 2 5 2003

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA1990 and 21 CFR 807.92.

The assigned 510(k) number is: K030035

Submitter:	Diametrics Medical, Inc. 2658 Patton Rd Roseville, MN 55113 Phone: (651) 638-1250 Fax: (651) 638-1060 Contact Person: Nancy Ring
Establishment Registration Number:	2183953
Summary Prepared on:	January 2, 2003
Identification of Device:	
Device Name:	Creatinine Cartridge
Proprietary Name:	IRMA® SL Blood Analysis System CR Cartridge
Common Name:	Creatinine Test System
Classification Name:	Enzymatic method, creatinine
Device Classification:	Class II
Regulation Number:	21 CFR 862.1225
Panel:	Chemistry (75)
Product Code:	JFY
Name of Predicate Device:	Vitros DT60 II Chemistry System / Vitros CRSC DT Slides
Predicate Device 510(k) Number:	K875191
Predicate Device Product Code:	75 JFY

Substantial Equivalence Claim

The IRMA® SL Blood Analysis System GL Cartridge is substantially equivalent in method, intended use and clinical performance to the currently marketed Vitros DT60 II Chemistry System / Vitros CRSC DT Slides.

Device Description
The IRMA® SL Blood Analysis System CR Creatinine Cartridge is for use with the IRMA®Blood Analysis System. The creatinine cartridge is a single use, disposable cartridge, for the in vitro measurement of creatinine in whole blood.

Samples are introduced via syringe or capillary injections with the IRMA® Capillary Collection Device. The creatinine sensor uses an enzymatic method for measuring creatinine. The IRMA® sensors are calibrated prior to each test using a calibrant packaged with the sensor. Calibration of the cartridge is completed when information determined at the factory for each lot of cartridges is combined with measurements taken during the calibration process. Factory derived calibration parameters are input into the analyzer by calibration code entry.

Throughout the calibration and analysis process, signals from the sensors are analyzed. If any abnormal conditions are detected, an error message is generated and the test will be terminated. If there are no abnormal conditions, then the sample results are displayed after successful calibration and analysis. In addition, the user has the option to print a hard copy of the results.

Intended Use
The CR cartridge is intended for professional use with the IRMA® Blood Analysis System for the direct measurement of creatinine, in human whole blood. The CR cartridge and the IRMA® Blood Analysis System are for in vitro diagnostic use.

Indications for Use
The measurement of creatinine aids in the diagnosis and treatment of certain renal diseases, and in monitoring renal dialysis.

Summary of Technological Characteristics
The following table shows comparison to the predicate device.

	IRMA®	Vitros DT60 II
Detection Method	Creatinine Oxidase	Creatinine amidohydrolase / creatinine amidinohydrolase / sarcosine oxidase
Measuring Range	Creatinine: 0.2 - 20.0 mg/dL (17.7 – 1768.5 mmol/L)	Creatinine: 0.05 - 16.5 mg/dL (4 - 1459 mmol/L)
Minimum Detection Limit	Creatinine: 0.04 mg/dl (3.5 mmol/L)	Not Specified
Operating Temp.	12-30°C (59-86°F)	15.5-35°C (60-85°F)
Operating Humidity	0-80%	15-75%
Sample	Whole blood 0.2 - 3.0 mL, from syringe 0.125 mL from capillary collection device	Serum or plasma 10 µL
Power	7.2 V NiCAD rechargeable battery or AC adapter	120 VAC 240 VAC
Reagents	Supplied in self-contained disposable cartridge	Supplied in a dry multi-layered film within a disposable plastic support
Weight	5 lbs.	19 lbs.
Results	Display and printer on board	Display and printer on board
Calibration	Automatic with each sample	Manual calibration with each new lot of Vitros DT slides, or when QC results using Vitros DT Controls are out of range

Summary of Performance Data:

Accuracy:

Analyte	n	Range evaluated	Slope	Intercept	r	Sy.x
Creatinine	110	0.5 - 10.1 mg/dl	0.94	0.16	0.981	0.55

Precision:

Level	N	IRMA Creatinine Mean (mg/dl)	IRMA Creatinine Total Precision sd	IRMA Creatinine Total Precision %CV
1	12	0.67	0.085	12.6
2	56	1.93	0.073	3.8
3	54	4.41	0.399	9.1
4	58	10.17	0.704	6.9
5	60	17.80	1.366	7.7
6	52	22.68	1.654	7.3

Linearity:

Analyte	n	Display Range	Assessment
Creatinine	20	0.2 – 20.0 mg/dl	Linear

Conclusions:

The data demonstrates that the Creatinine Cartridge is as safe, effective and performs as well as the legally marketed predicate device to which equivalence is claimed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 25 2003

Ms. Nancy Ring
QA/RA Manager
Diametrics Medical
2658 Patton Road
Saint Paul, MN 55113-1136

Re: k030035
Trade/Device Name: IRMA® SL Blood Analysis System CR cartridge
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: JFY
Dated: April 11, 2003
Received: April 14, 2003

Dear Ms. Ring:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. 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 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

K030035

Statement of Indications For Use

Intended Use

The CR cartridge is intended for professional use with the IRMA® Blood Analysis System for the direct measurement of creatinine, in human whole blood. The CR cartridge and the IRMA® Blood Analysis System are for in vitro diagnostic use.

Indications for Use

Creatinine measurements are used in the diagnosis and treatment of certain renal disease, and in monitoring renal dialysis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Albert Smith for Joan Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030035