DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 3 1 2006

Dr. Pauline Armstrong
QA/Regulatory Affairs Manager
Randox Laboratories Ltd.
55 Diamond Road
Crumlin, Co. Antrim
BT29 4QY
United Kingdom

Re: k052914
Trade/Device Name: RX Imola, (Clinical Chemistry Analyser), ISE Unit & Magnesium Test Kit
Regulation Number: 21 CFR§ 862.1600
Regulation Name: Potassium test system
Regulatory Class: Class II
Product Code: CEM, CGZ, JGS, JGJ, JJE
Dated: February 20, 2006
Received: February 22, 2006

Dear Dr. Armstrong:

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **NOT KNOWN**

Device Name: **RX Imola, (Clinical Chemistry Analyser), ISE Unit & Magnesium Test Kit**

Indications For Use:

The RX Imola is a medium-sized desktop fully Automated Clinical Chemistry Analyzer complete with Ion Selective Electrode (ISE) Unit and dedicated analyzer software. An external PC operates the analyzer and results can be printed as required. The analyzer may be connected to a host computer, when required.

The analyzer can be used to run tests such as magnesium in serum and plasma samples. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia and hypermagnesemia. Various other clinical chemistry assays are adaptable to the analyzer.

The ISE Unit on the RX Imola can be used for measurement of the electrolytes sodium, potassium and chloride in serum, plasma and urine and for use in diagnosis and treatment of electrolyte imbalance.

The RX Imola analyzer must only be used by suitably qualified personnel, under appropriate laboratory conditions.

For *in vitro* diagnostic use only.

Prescription Use ___✓____ AND/OR Over-The-Counter Use __
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson

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