



DEC - 4 2003

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dr. Lynne Hamilton
Regulatory Affairs
Randox Laboratories, Limited
55 Diamond Road
Crumlin, County Antrim
United Kingdom BT29 4QY

Re: k024014
Trade/Device Name: RX DAYTONA
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA, JGS, CEM, CGZ, JJF, JIX
Dated: September 3, 2003
Received: September 5, 2003

Dear Dr. Hamilton:

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.

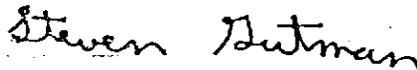
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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). Other general information on your responsibilities under the Act may be obtained 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

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

510(k) Number (if known) K024014

Device Name RX DAYTONA

(CLINICAL CHEMISTRY ANALYSER)

Indications For Use:

The RX Daytona is an automated clinical chemistry analyser complete with dedicated analyser software. Software functions of the analyser include the facility to interact with a host computer for direct download of test method selection details for individual samples. A barcode system is used for the rapid identification of patient samples, reagents and QC samples.

The analyser can be used to run tests including glucose in serum samples. Various other assays are adaptable to the analyser. Glucose measurements may be used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia and pancreatic islet cell carcinoma.

An Ion Selective Electrode (ISE) unit is an optional addition, which may be used with the RX Daytona Analyser for the measurement of the electrolytes sodium, potassium and chloride in serum, or urine. The ISE unit consists of ion selective electrodes, supply and drain pump, preamplifier board and I/O board.

Sodium measurements may be used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion or other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases characterised by low or high levels of potassium. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

The RX Daytona analyser and ISE unit must only be used by suitably qualified personnel, under appropriate laboratory conditions.

For *in vitro* diagnostic use only.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol Benson & Jean Cooper, DVM
Division Sign-Off

**Office of In Vitro Diagnostic Device
Evaluation and Safety**

510(k) K024014

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter
(Optional form)