DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 12 2003

Dr. Lynne Hamilton
Regulatory Affairs
Randox Laboratories Ltd.
Biochemical Manufacturers
Ardmore, Diamond Road
Crumlin, Co. Antrim
United Kingdom, BT29 4QY

Re: k030873
Trade/Device Name: Randox Ammonia
Regulation Number: 21 CFR 862.1065
Regulation Name: Ammonia test system
Regulatory Class: Class I
Product Code: JIF
Dated: March 18, 2003
Received: March 20, 2003

Dear Dr.Ambrose:

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

K030873

510(k) Number (if known) ~~Unknown~~

Device Name Ammonia

Randox Ammonia

Indications For Use :

The Randox Laboratories Limited Ammonia Test Kit is an *in vitro* diagnostic assay for the quantitative determination of ammonia in plasma. During the assay ammonia combines with α-ketoglutarate and NADPH in the presence of glutamate dehydrogenase (GLDH) to yield glutamate and $NADP^+$. The corresponding decrease in absorbance at 340nm is proportional to the concentration of ammonia in the plasma.

Ammonia measurememts are used in the diagnosis and treatment of severe liver disorders, such as cirrhosis, hepatitis and Reye's Syndrome.

This application sheet has been developed for the Advia 1650 analyser and must be used by suitably qualified laboratory personnel under appropriate laboratory conditions.

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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030873