DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Randox Laboratories, Ltd.
c/o Dr. Pauline Armstrong
55 Diamond RD.
Crumlin County Antrim
United Kingdom BT29 4QY

Re: k092273
Trade/Device Name: Randox Ethanol Assay and Randox Ethanol Calibrators and Controls
Regulation Number: 21 CFR 862.3040
Regulation Name: Alcohol test system
Regulatory Class: Class II
Product Code: DIC, DLJ and LAS
Dated: September 14, 2010
Received: September 16, 2010

NOV - 1 2010

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 ) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

## Indication for Use

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510(k) Number (if known): K092273

Device Name: RANDOX ETHANOL ASSAY AND THE RANDOX ETHANOL CALIBRATOR/CONTROL SET

Indication For Use:

**Randox Ethanol Assay**

The Randox Ethanol Assay is an in vitro diagnostic test for the quantitative analysis of Ethanol in human urine and serum on the ***f*X series** analysers, which includes the ***f*X daytona™** and the ***f*X imola™** analysers.

The measurement of ethanol is used for the diagnosis and treatment of alcohol intoxication and poisoning.

This is an in vitro diagnostic device intended for prescription use only.

**Randox Ethanol Calibrator Set**

The Randox Ethanol Calibrator Set is intended for the calibration of the Randox Ethanol assay, which is used for the quantitative analysis of ethanol in human urine and serum on the ***f*X series** analysers which includes the ***f*X daytona™** and the ***f*X imola™**.

**Randox Ethanol Control Set**

The Randox Ethanol Control Set is intended for the quality control of the Randox Ethanol assay, which is used for the quantitative analysis of ethanol in human urine and serum on the ***f*X series** analysers which includes the ***f*X daytona™** and the ***f*X imola™**.

This is an in vitro diagnostic device intended for prescription use only.

Prescription Use ___✓___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092273