DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 13 2006

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

Re: k053153
Trade/Device Name: Randox Calibration Serum
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: October 28, 2005
Received: November 15, 2005

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: CALIBRATION SERUM LEVELS 2 & 3

Indications For Use:

This is an *in vitro* diagnostic product intended for use as a calibration serum in clinical chemistry assays. Randox calibration serum contains 43 analytes and is based on lyophilized human serum. The concentrations and activities are suitable for calibration of clinical chemistry assays both manually and on a wide range of automatic analysers. Constituent concentrations are available at 2 levels.

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

K053153

CALIBRATION SERUM LEVELS 2 & 3 - Catalogue Numbers CAL2350 & CAL2351

Analyte	Analyte
Albumin	
Aldolase	Gamma-GT
Alkaline Phosphatase	GLDH
ALT (GPT)	Glucose
Amylase Pancreatic	α-HBDH
Amylase Total	Iron
Acid Phosphatase (non-prostatic)	Lactate
Acid Phosphatase (Prostatic)	LAP
Acid Phosphatase (Total)	LD (LDH)
AST (GOT)	Lipase
Bile Acids	Lithium
Bicarbonate	Magnesium
Bilirubin Direct	Osmolality
Bilirubin Total	Phosphate Inorganic
Calcium	Potassium
Cholesterol	Protein Total
Chloride	Sodium
Cholinesterase	TIBC
CK Total	Triglycerides
Copper	Uric Acid (Urate)
Creatinine	Urea
D-3-Hydroxybutyrate	Zinc

Carol Benson

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