DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

JUL 20 2006

Re: k061056
Trade/Device Name: Randox Liquid Protein Calibrators (For Neat Sample Assays)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrators
Regulatory Class: Class II
Product Code: JIX
Dated: April 11, 2006
Received: April 17, 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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K061056

Device Name: LIQUID PROTEIN CALIBRATORS (for neat sample assays)

Indications For Use:

The Randox Laboratories Limited Liquid Protein Calibrator (for neat sample assays) is derived from normal human serum obtained from volunteer donors. It has been developed for the calibration of ASO, Complement C3, Complement C4, CRP, Ferritin, IgA, IgG, IgM, Prealbumin, Transferrin and Haptoglobin assays (all neat sample assays).
Assignment was performed at Randox Laboratories by immunoturbidimetry with reference to International Reference Material CRM 470. The constituent concentrations of these Calibrators are present at levels 1, 2, 3, 4 and 5.

This calibrator can be used on Abbott Spectrum, Abbott aeroset, Abbott Architect *i*2000, Architect *i*2000sr, Ace Analyser, Bayer Advia 1650, Advia 2400, Advia 1200, Dade Dimension RXL, Dimension AR, Hitachi 704, Hitachi 717, Hitachi 911, Hitachi 917, Hitachi 912, Hitachi 747, Kone progress, Olympus AU800, AU600, AU400, AU2700, AU5400, Selectra vitalab, Synchron CX4 Synchron CX5 Synchron CX7, Synchron LX20, ILAB300, ILAB900, ILAB1800, ILAB600, RX Daytona, RX Imola, Cobas Mira, Cobas Mira S, Cobas Mira plus systems

The Randox Laboratories Limited Liquid Protein Calibrators, should only be used by suitably qualified laboratory personnel under appropriate laboratory conditions.

For in vitro diagnostic use.

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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)

Maria M Chan
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K061056