K121746

1. SAFETY AND EFFECTIVENESS AS REQUIRED BY 21 CFR 807.92

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirement 21 CFR 807.92.

JUL 11 2012

2. SUBMITTER NAME AND ADDRESS

Name: Randox Laboratories Limited

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United Kingdom.

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3. DEVICE PROPRIETARY NAME, COMMON NAME, PRODUCT CODE CLASSIFICATION AND 21 CFR NUMBER

Device Proprietary Name: Randox Microalbumin Control Level 1 and Level 2 (Liquid)

Common Names: Microalbumin Control Level 1 and Level 2

Product Code: JJX

Classification: Single (Specified) Analyte Controls (Assayed and Unassayed) Class I, reserved

21 CFR Number: 21 CRF 862.1660

4. PREDICATE DEVICE PROPRIETARY NAME AND 510 (k) NUMBER

Predicate Device Proprietary Name: LIQUICHEK™ Microalbumin Control Levels 1 and 2

510 (k) Number: K072835

5. INTENDED USE

The Randox Microalbumin controls are designed for *in vitro* diagnostic use as assayed quality control materials for the quantitative determination of albumin in human urine.

6. DEVICE DESCRIPTION

Randox Microalbumin Controls are manufactured at two levels, Level 1 and Level 2. They are single analyte controls made with human serum. The analyte concentrations in each control have been reviewed by a panel of experts to ensure that the concentrations are clinically relevant for use in routine hospital laboratories.

7. PREDICATE DEVICE COMPARISON TABLE

CHARACTERISTICS	RANDOX MICROALBUMIN CONTROL LEVEL 1 AND CONTROL LEVEL 2	LIQUICHEK™ MICROALBUMIN CONTROL LEVELS 1 AND 2 K072835
INTENDED USE	Randox Microalbumin Control Levels 1 and 2 are designed for in vitro diagnostic use as assayed quality control materials for the quantitative determination of albumin in human urine.	Liquichek Microalbumin Control is intended for use as assayed quality control urine to monitor the precision of laboratory testing procedures for the analytes Microalbumin and Creatinine.
SIZE	Microalbumin Liquid Controls 6x1mls	Level 1 12x10mls Level 2 12x10mls Bilevel Mini Pak 2x10mls
FORMAT	Liquid	Liquid
MATRIX	Prepared from Human Serum	Prepared from Human Urine
STORAGE (Unopened)	The Microalbumin Liquid Controls are supplied ready for use and are stable up to the expiry date when capped and stored at +2 to +8°C.	The Liquichek Microalbumin controls are supplied ready for use and are stable up to the expiry date when capped and stored at +2 to +8°C.
ANALYTES	Microalbumin	Microalbumin Creatinine

8. SUMMARY OF STABILITY STUDIES

OPENED: Store refrigerated (+2°C to +8°C). Microalbumin is stable for 28days if kept capped in the original container and free from contamination. Only the required amount of product should be removed.

UNOPENED: Store refrigerated (2°C to +8°C). Stable to the expiration date printed on the individual vials.

9. SUMMARY OF VALUE ASSIGNMENT

10 reps were run on the following analysers, Hitachi 717, Cobas Mira, RX Daytona and Dimension. One lot of previous control material was assessed to validate the run. A target was assigned based on the average of all the results from the various analysers and a range of +/- 20% was applied.

The CV% and % recovery error result should fall within the range shown below.

PRODUCT NUMBER(S)	TARGET VALUE	ACCEPTABLE MANUFACTURING RANGE	%CV	% RECOVERY ERROR
MA041 (Level 1)	30 mg/L	20 - 40 mg/L	≤ 5	≤ 5
MA042 (Level 2)	150 mg/L	130 – 170 mg/L	≤ 5	≤ 5

10. TRACEABILITY

ANALYTE	SUPPLIER	PRODUCT NUMBER	ORIGIN	SOURCE
Microalbumin	Sigma	A-8763	Human	Human Serum

11. CONCLUSION

Testing results indicate that the proposed device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

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

JUL 11 2012

Re: k121746
Trade Name: Randox Microalbumin Control Level 1 and Level 2 (Liquid)
Regulation Number: 21 CFR §862.1660
Regulation Name: Single (Specified) Analyte Controls (Assayed)
Regulatory Class: Class I, reserved
Product Codes: JJX
Dated: June 14, 2012
Received: June 14, 2012

Dear Ms. 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 H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology 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):

Device Name: Randox Microalbumin Control Level 1 and Control Level 2

Indication for Use:

The Randox Microalbumin Liquid Controls are designed for use as assayed quality control materials for the quantitative determination of albumin in human urine.

This in vitro diagnostic device is intended for prescription use only and can only be used by professionals.

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 Devices (OIVD)

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

510(k) K121746