MAR 2 5 2014 K140393

510 (k) Summary

1. SAFETY AND EFFECTIVENESS AS REQUIRED BY 21 CFR 807.92 STATEMENT

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

2. SUBMITTER NAME AND ADDRESS

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Date of Summary Preparation: March 19, 2014

3. 510k NUMBER, DEVICE PROPRIETARY NAME, COMMON NAME, PURPOSE FOR SUBMISSION, REGULATORY CLASSIFCATION, PANEL, PRODUCT CODE AND 21 CFR NUMBER

510k No: K140393

Device Proprietary Name: Randox Ammonia Ethanol Control Levels 1, 2 & 3

Common Name: Randox Ammonia Ethanol Control Levels 1, 2 & 3

Purpose for Submission: New Device

Regulatory Classification: Multi-analyte Controls, All kinds (Assayed and Unassayed)

Panel: Clinical Chemistry

Product Code: JJY

21 CFR Number: 21 CFR 862.1660

4. PREDICATE DEVICE PROPRIETARY NAMES AND 510 (k) NUMBERS

Predicate Device Proprietary Name:
Liquichek Ethanol/ Ammonia Control

510 (k) Number: K123198

5. INTENDED USE

The Randox Ammonia Ethanol Control Levels 1, 2 & 3 are intended for in vitro diagnostic use in the quality control of Ammonia and Alcohol Assays to monitor precision and to detect systematic analytical deviations on clinical chemistry systems. This device is for prescription use only

6. DEVICE DESCRIPTION

The Randox Ammonia Ethanol Controls are liquid and supplied at levels 1, 2 and level 3. The base matrix used for the manufacture of Randox Ammonia Ethanol Controls Levels 1, 2 & 3 is saturated benzoic acid with added chemicals.

Each level of control is supplied in liquid form in 6 x 2ml vials and is ready for use. Only the required amount of product should be removed from the vial. After use, any residual product should not be returned to the original vial.

7. PREDICATE DEVICE COMPARISON TABLE

COMPARISON OF RANDOX AMMONIA ETHANOL CONTROL LEVELS 1, 2 AND 3 WITH THE PREDICATE DEVICE

CHARACTERISTICS	RANDOX ETHANOL CONTROL LEVELS 1, 2 AND 3 *(New Device)*	BIO-RAD LABORATORIES LIQUICHEK ETHANOL/AMMONIA CONTROL K123198 *(Predicate Device)*
SIMILARITIES		
INTENDED USE	The Randox Ammonia Ethanol Control Levels 1, 2 & 3 are intended for in vitro diagnostic use in the quality control of Ammonia and Alcohol Assays to monitor precision and to detect systematic analytical deviations on clinical chemistry systems. This device is for prescription use only.	Liqichek Ethanol/Ammonia Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for Ammonia and Alcohol assays.
FORMAT	Liquid	Liquid
STORAGE (Unopened)	2 to 8 ^{0}C Until expiration date	2 to 8 ^{0}C Until expiration date
DIFFERENCES		
MATRIX	Saturated Benzoic acid with added chemicals.	Bovine serum albumin with added chemicals, stabilisers and preservatives.
OPEN VIAL CLAIM	30 days at +2 to 8°C.	20 days at +2 to 8°C on board Siemens Dimension Vista instrument.
SIZE	2ml	2.5ml
SHELF LIFE	18 months	24 months

8. SUMMARY OF STABILITY STUDIES

Open vial stabiltiy

Open vial stability of the Randox Ammonia Ethanol Control Levels 1, 2 & 3 was assessed by opening a set of Randox Ammonia Ethanol Control levels 1, 2 & 3 and handling them according to the package insert. Vials were stored at +2 to +8°C for 7, 14, 21 and 30 days and tested on the ADVIA 1650 for Ammonia and RX Daytona for Ethanol.

The acceptance criteria state the percentage deviation of open vial material to fresh material should be ≤5%.

The table below shows the summary of the open vial stability at Day 30.

Results

Open Vial Stability Day 30

Ammonia Analyte on the ADVIA 1650	Open Vial Result (µmol/l)	Fresh Result (µmol/l)	% Difference
Level 1	55.19	54.79	0.7%
Level 2	151.24	152.60	-0.9%
Level 3	284.35	290.27	-2.0%

Ethanol Analyte on the RX Daytona	Open Vial Result (mg/dl)	Fresh Result (mg/dl)	% Difference
Level 1	51.83	49.50	4.7%
Level 2	165.04	163.16	1.2%
Level 3	292.18	387.22	1.3%

The data demonstrates that the Randox Ammonia Ethanol Control levels 1, 2 & 3 are stable for 30 days at + 2 to 8°C.

Real Time Testing

The Randox Ammonia Ethanol Control levels 1, 2 & 3 were stored at ultra frozen conditions -75 to -90°C. Following storage at the ultra frozen temperature, the controls were then tested and on the ADVIA 1650 for Ammonia and RX Daytona for Ethanol alongside control material stored unopened at the routine storage temperature of +2 to +8°C at various timepoints and the percentage deviation is calculated.

The acceptance criteria state the percentage deviation to controls stored at the routine temperature should be ≤5%.

Current Real Time studies support a 18 month shelf life.

9. SUMMARY OF VALUE ASSIGNMENT

Value assignment is used to calculate an assigned value for the Randox Ammonia Ethanol Control Levels 1, 2 & 3. The value assignment process for the Randox Ammonia Ethanol controls is based on the master lot concept. The value is assigned by performing nested testing of the new lot of control against the master lot on a clinical chemistry analyser (ADVIA 1650 for Ammonia, RXDaytona for Ethanol). Multiple replicates of the test calibrator and controls are assessed on the clinical chemistry analyser and the mean and CV calculated. The recovery of the master lot is also measured.

The acceptance criteria states the precision measured by the CV should be less than or equal to 10% for Control Level 1 and less than or equal to 7.5% for Control Levels 2 and Level 3. The recovery error of the master lot is also measured and should be ≤ 7.5% for all control levels.
An assigned value is calculated and a +/-20% range applied.

Control ranges stated in the package insert are summarized in the tables below.

LEVEL 1				
ANALYTE	**SYSTEM**	**METHOD**	**TARGET**	**RANGE**
AMMONIA (µmol/l)	ADVIA 1650	Enzymatic (UV)	55	44 - 66
ETHANOL (g/l)	RX Daytona	Enzymatic (UV)	0.51	0.41 - 0.61
ETHANOL (mg/dl)	RX Daytona	Enzymatic (UV)	51	41 - 61

LEVEL 2				
ANALYTE	**SYSTEM**	**METHOD**	**TARGET**	**RANGE**
AMMONIA (µmol/l)	ADVIA 1650	Enzymatic (UV)	141	113 – 169

ETHANOL (g/l)	RX Daytona	Enzymatic (UV)	1.47	1.18 – 1.76
ETHANOL (mg/dl)	RX Daytona	Enzymatic (UV)	147	118 – 176

LEVEL 3				
ANALYTE	**SYSTEM**	**METHOD**	**TARGET**	**RANGE**
AMMONIA (µmol/l)	ADVIA 1650	Enzymatic (UV)	297	238 - 356
ETHANOL (g/l)	RX Daytona	Enzymatic (UV)	3.76	3.01 - 4.51
ETHANOL (mg/dl)	RX Daytona	Enzymatic (UV)	376	301 - 451

10. CONCLUSION

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2014

RANDOX LABORATORIES LIMITED
PAULINE ARMSTRONG
55 DIAMOND RD.
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UK

Re: K140393
Trade/Device Name: Randox Ammonia Ethanol Control Levels 1, 2 and Level 3
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJY
Dated: February 11, 2014
Received: February 21, 2014

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
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Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k140393

Device Name
Randox Ammonia Ethanol Controls Levels 1, 2, & 3

Indications for Use *(Describe)*
The Randox Ammonia Ethanol Controls Levels 1, 2, & 3 are intended for in vitro diagnostic use in the quality control of Ammonia and Alcohol Assays to monitor precision and to detect systematic analytical deviations on clinical chemistry systems. This device is for prescription use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S

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