K132090

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

AUG 8 2013

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

510k No: -

Device Proprietary Name: Randox Benzodiazepine Calibrator Set and Randox Benzodiazepine Controls Level 1 and 2

Common Name:
Benzodiazepine Calibrators Set (Levels 0, 1, 2, 3 and 4)
Benzodiazepine Controls Levels 1 and 2

Purpose for Submission: New Device

Regulatory Classification:
Calibrators Drug Specific
Clinical Toxicology Control Material

Panel: Toxicology

Product Code: DLJ & LAS

21 CFR Number: 21 CFR 862.3200 & 21CFR 862.3280

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

Predicate Device Proprietary Name:
Lin-Zhi International, Inc, LZI Multiple Analyte Urine Drugs of Abuse Calibrators and Controls

510 (k) Number: K051088

5. INTENDED USE

Randox Benzodiazepine Calibrator Set
The Randox Benzodiazepine Calibrator set consists of liquid calibrators containing Oxazepam. There are 5 levels of calibrator. They have been developed for use in the calibration of the RX series analysers in human urine, which includes the RX Daytona and the RX Imola. This *in vitro* diagnostic device is intended for prescription use only.

Randox Benzodiazepine Controls Level 1 & 2
The Randox Benzodiazepine Controls are liquid controls containing Oxazepam. There are 2 levels of controls. They have been developed for use in the quality control and validation of Benzodiazepine assay on the RX series analysers in human urine, which includes the RX Daytona and the RX Imola. This *in vitro* diagnostic device is intended for prescription use only.

6. DEVICE DESCRIPTION

The Benzodiazepine Calibrator Set contains 5 levels of calibrator containing the specific drug Oxazepam. The Calibrators are spiked at 4 different levels which assess below, at and above the cutoff of 200 ng/ml.

The Benzodiazepine Controls are manufactured at two levels, one below the cutoff and one above the cutoff of 200 ng/ml.

The base matrix used for the manufacture of Randox Benzodiazepine Calibrators and Controls is Drug Free Human Urine.

The Benzodiazepine Calibrators and Controls contain the specific drug Oxazepam. The Oxazepam is supplied by Cerilliant Corporation the accuracy of which is ensured by purity determinations (GC/FID, HPLC and NMR) and gravimetric preparation using balances calibrated with NIST traceable weights.

Randox Benzodiazepine Calibrators and Controls have been designed for *in vitro* diagnostic use only. They should not be pipetted by mouth and the normal precautions for handling laboratory reagents should be applied. Randox Benzodiazepine Calibrators and Controls contain sodium azide at 0.05%.

7. PREDICATE DEVICE COMPARISON TABLE

Similarities		
CHARACTERISTICS	**RANDOX BENZODIAZEPINE CALIBRATORS AND CONTROLS**	**LIN-ZHI DRUG MIXTURE CALIBRATOR AND CONTROLS K051088**
FORMAT	Liquid calibrators and controls	Same
MATRIX	Urine matrix for calibrators and controls	Same

Differences		
CHARACTERISTICS	**RANDOX BENZODIAZEPINE CALIBRATORS AND CONTROLS**	**LIN-ZHI DRUG MIXTURE CALIBRATOR AND CONTROLS K051088**
INTENDED USE	The Randox Benzodiazepine Calibrator set consists of liquid calibrators containing Oxazepam. There are 5 levels of calibrator. They have been developed for use in the calibration of the RX series analysers in human urine, which includes the RX Daytona and the RX Imola. This *in vitro diagnostic* device is intended for prescription use only. The Randox Benzodiazepine Controls are liquid controls containing Oxazepam. There are 2 levels of controls. They have been developed for use in the quality control and validation of Benzodiazepine assay on the RX series analysers in human urine, which includes the RX Daytona and the RX Imola. This *in vitro* diagnostic device is intended for prescription use only.	Intended for in vitro diagnostic use for the calibration and validation of LZI DAU enzyme immunoassays to detect methamphetamine, opiate, phencyclidine, benzoylecgonine, barbiturates, methadone, and propoxyphene in human urine
LEVELS	Calibrators: there are a total of 5 levels, including negative Controls: there are two levels	Total of 7 levels, including negative
STORAGE (Unopened)	Calibrators and Controls: when not in use bottles should be capped at all times and refrigerated at 2-8°C until expiration date.	Calibrators and Controls when not in use bottles should be capped at all times and refrigerated at 2-8°C.
OPEN VIAL CLAIM	Calibrators and Controls are stable for 28 days after opening capped and stored at 2-8°C	Unknown
DRUGS	Calibrators and Controls: Benzodiazepine Oxazepam	Multianalyte Methamphetamine, Opiate Phencyclidine, Benzolecgonine Benzodiazepines, Barbiturates Methadone, Propoxyphene

8. SUMMARY OF STABILITY STUDIES

Open vial stability of the Benzodiazepine Calibrators and Controls level 1 and 2 were assessed by opening a set of calibrators and controls, replacing the caps and storing at +2°C to +8°C for 28 days. At day 7, 21 and 28 an aliquot was removed for assessment. The recovery of each calibrator and control was compared to a freshly opened set of calibrators and controls at day 7, 21 and 28. The acceptance criteria was the percentage deviation of the fresh vial compared to the open vial at each time point should be less than or equal to 10%. Table 1 below shows a summary of the open vial stability for Benzodiazepine calibrators and controls. The instrument used for this assessment was the Randox Imola (k052914). The assay used was the Benzodiazepine Assay (k092274).

Table 1

Batch Lot	Material	Time point		
		Day 7	Day 21	Day 28
242516	Calibrators 1-4	Pass	Pass	Pass
51110	Calibrators 1-4	Pass	Pass	Pass
61110	Calibrators 1-4	Pass	Pass	Pass
250-251DA	Controls 1-2	Pass	Pass	Pass
51110	Controls 1-2	Pass	Pass	Pass
61110	Controls 1-2	Pass	Pass	Pass

The data demonstrates that the Benzodiazepine Calibrators and Controls for three batches are stable for 28 days when opened, recapped and stored at +2°C to +8°C.

Shelf life for Benzodiazepine Calibrators was assessed by real time stability studies and accelerated stability studies. Once a new batch of calibrators are manufactured, 5 calibrator sets are set aside and stored at +2°C to +8°C. After 1, 3, 6, 9 and 12 months as set of calibrators are assessed and compared to day 0 calibrators. The acceptance criteria states the calibration absorbance achieved at each time point should be 100% ±10% when compared to the fresh assessment. The instrument used for this assessment was the Randox Imola (k052914). The assay used was the Benzodiazepine Assay (k092274).

Table 2

Batch Lot	Material	Time point in months				
		1	3	6	9	12
023-027DA	Calibrators 1-4	Pass	Pass	Pass	Pass	Pass

The data demonstrates in table 2 that the Benzodiazepine calibrators were stable for 12 months at +2°C to +8°C when stored unopened.

Accelerated stability studies were used to predict the shelf life of the Benzodiazepine calibrator set. Six sets of Benzodiazepine calibrators were stored at +37°C for 1, 3, 5, 7, 10 and 12 days. At each time point the calibration absorbance's achieved are compared to those achieved at Day 0. Storage at +37°C for 5 days is equivalent to 12 months shelf life.

Table 3

Batch Lot	Material	Time point in Days					
		1	3	5	7	10	12
023-027DA	Calibrators 1-4	Pass	Pass	Pass	Pass	Pass	Pass

The data demonstrates in table 3 that the Benzodiazepine calibrators are stable for at least 12 months at +2°C to +8°C when stored unopened.

Real time stability testing for Benzodiazepine Controls. Following the manufacture of Benzodiazepine controls 5 sets are set aside and stored at +2°C to +8°C. At 3, 4, 6, 9 and 12 months a set of controls are assessed. The acceptance criteria for Benzodiazepine control 1 states the concentration should be less than the cutoff of 200 ng/ml and for Benzodiazepine control 2 the concentration should be greater than the cutoff of 200ng/ml.

Batch Lot	Material	Time point in Months				
		3	4	6	9	12
482DA	Controls 1-2	Pass	Pass	Pass	Pass	Pass
483DA	Controls 1-2	Pass	Pass	Pass	Pass	Pass

The data demonstrates that the Benzodiazepine Controls are stable for at least 12 months at +2°C to +8°C when stored unopened.

9. SUMMARY OF VALUE ASSIGNMENT

A concentration is calculated for each new batch of Randox Benzodiazepine Calibrators and Controls by nest testing. Nest testing involves assessment of the new lot of controls against a master lot of controls or calibrators. Ten replicates of the test calibrators/controls are assessed 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 15%. The recovery error of the master lot is also measured and should be ± 10% for all calibrator and control levels. The instrument used for this assessment was the Randox Imola (k052914). The assay used was the Benzodiazepine Assay (k092274).

Please see summary table below.

Calibrator / Control Level	Lot #	Concentration of Oxazepam (ng/ml)
Calibrator Level 1	584DA	100
Calibrator Level 2	585DA	200
Calibrator Level 3	586DA	300
Calibrator Level 4	587DA	1000
Control Level 1	596DA	150
Control Level 2	597DA	250

10. TRACEABILITY

The Benzodiazepine Calibrators and Controls are prepared using drug free human urine as the base material. Oxazepam is spiked into the calibrators and controls at various concentrations. The Oxazepam is supplied by Cerillant Corporation the accuracy of which is ensured by purity determinations (GC/FID, HPLC and NMR) and gravimetric preparation using balances calibrated with NIST traceable weights.

11. CONCLUSION

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

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

August 8, 2013

Randox Laboratories Limited
C/O Dr. Pauline Armstrong
55 Diamond Road, Crumlin
County Antrim, BT29 4QY
UNITED KINGDOM

Re: K132090
Trade/Device Name: Randox Benzodiazepine Calibrator Set
Randox Benzodiazepine Controls Level 1 and 2
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: II
Product Code: DLJ, LAS
Dated: July 3, 2013
Received: July 15, 2013

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 Part 801); 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 regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Carol C. Benson -S for

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

Enclosure

Indications for Use

510(k) Number (if known): k132090

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Randox Benzodiazepine Controls Level 1 and 2

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Prescription Use _X_ (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 Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.08.08 07:32:10 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k132090