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

April 28, 2017

RANDOX LABORATORIES LTD
PAULINE ARMSTRONG
QA/RA MANAGER
55 DIAMOND ROAD
CRUMLIN BT29 4QY GB

Re: K162200
Trade/Device Name: Randox Rx Daytona Plus Magnesium (MG)
Regulation Number: 21 CFR 862.1495
Regulation Name: Magnesium test system
Regulatory Class: II
Product Code: JGJ
Dated: March 22, 2017
Received: March 24, 2017

Dear Pauline 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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Kellie B. Kelm -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

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)*
k162200

Device Name
Randox RX daytona plus magnesium (Mg)

Indications for Use *(Describe)*
The Randox RX daytona plus magnesium (Mg) test system is intended for the quantitative in vitro determination of magnesium concentration in serum, urine and lithium heparinized plasma. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low levels of magnesium) and hypermagnesemia (abnormally high levels of magnesium).

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY, RANDOX RX DAYTONA PLUS MAGNESIUM (MG) REAGENT

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

Name: Dr. Pauline Armstrong

Address: Randox Laboratories Limited
55 Diamond Road, Crumlin,
County Antrim, BT29 4QY,
United Kingdom.

Telephone: +44 (0) 28 9442 2413
Fax: +44 (0) 28 9445 2912
E-mail: Pauline.Armstrong@randox.com

Date of Summary Preparation: 28 April 2017

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

510k No: k162200

Device Proprietary Name: Randox RX **daytona plus** magnesium (Mg)

Common Name: RX **daytona plus** magnesium (Mg)

Purpose for Submission: New Device

Product Code	Regulation Name	Classification	Regulation Section	Panel
JGJ	Magnesium Test System	Class I, reserved	21 CFR §862.1495 Magnesium Test System	Clinical Chemistry (75)

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

Predicate Device Proprietary Name: Siemens Magnesium (MG)

510 (k) Number: k991576

5. INTENDED USE

The Randox RX **daytona plus** magnesium (Mg) test system is intended for the quantitative in vitro determination of magnesium concentration in serum, urine and lithium heparinized plasma. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low levels of magnesium) and hypermagnesemia (abnormally high levels of magnesium).

6. DEVICE DESCRIPTION

The Magnesium kit assay consists of a ready to use reagent solution.

CATALOGUE NUMBER: MG8326

R1. Color Reagent 2 x 16.5 mL

REAGENT COMPOSITION

Contents	Initial Concentrations Of Solutions
R1. Colour Reagent	
Xylidyl blue	0.1 mmol/L
Tris Buffer	0.2 mmol/L
Potassium Carbonate	77 mmol/L
EGTA	0.04 mmol/L

Materials required but not provided.

Randox Assayed Multi-sera Level 2, (Cat no. HN1530 and Level 3, HE1532, both cleared under k942458)
Randox Calibration Serum Level 3, (Cat no. CAL2351, cleared under k053153)
RX series Saline (Cat. No. SA8396)
RX series Acid Wash Solution (Cat. No. WS8397)

7. PREDICATE DEVICE COMPARISON TABLE

Table 1 Comparison of Randox RX **daytona plus** magnesium (Mg) to the predicate device

Characteristics	Randox RX daytona plus magnesium (Mg) *(Candidate Device)*	Siemens Magnesium (MG) *(Predicate Device)*
Intended Use	The Randox RX **daytona plus** magnesium (Mg) test system is intended for the quantitative in vitro determination of magnesium concentration in serum, urine and lithium heparinized plasma. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low levels of magnesium) and hypermagnesemia (abnormally high levels of magnesium)	For the quantitative *in vitro* determination of magnesium concentration in human plasma, serum and urine on ADVIA Chemistry systems
Assay Protocol	Colorimetric Method	Same
Test Principle	Magnesium ions react with xylidyl blue in an alkaline medium to form a water soluble purple-red chelate, the colour intensity of which is proportional to the concentration of magnesium in the sample. Calcium is excluded from the reaction by complexing with EGTA.	Same
Sample Type	Serum, urine and lithium heparinized plasma	Same
Storage (Unopened)	Reagents are stable up to the expiry date when stored unopened at +2 to +8°C	Same
Control Frequency	Randox Assayed Multi-sera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day.	Siemens recommends the use of commercially available quality control materials with at least 2 levels (low and high). Analyse at least 2 levels of controls daily.
Calibration	0.9% NaCl solution and Randox Calibration Sera Level 3 are recommended for calibration.	Siemens Chemistry Calibrator REF 09784096 (T03-1291-62)
Reagent Composition	**R1. Colour Reagent** Xylidyl blue 0.1 mmol/L Tris Buffer 0.2 mmol/L Potassium Carbonate 77 mmol/L EGTA 0.04 mmol/L	**Reagent 1** Tris buffer 500 mmol/L Sodium azide 0.09% **Reagent 2** Xylidyl blue 0.28 mmol/L Sodium azide 0.09%
Measuring Range	Serum 0.74 – 4.95 mg/dl Urine 1.01 – 23.82 mg/dl	Serum 0.7 - 5.0 mg/dl Urine 0.5 - 25.0 mg/dl

8. TEST PRINCIPLE [1-5]

Magnesium ions react with xylidyl blue in an alkaline medium to form a water soluble purple-red chelate, the colour intensity of which is proportional to the concentration of magnesium in the sample. Calcium is excluded from the reaction by complexing with EGTA.

1. Mann, C.K., Yoe, J.H., Anal. Chem. 1956, **28:** 202-205.
2. Mann, C.K., Yoe, J.H., Anal. Chim. Acta (1957), **16:** 155-160.
3. Ogata, H., Hiroi, L., Anal. Chem. (1959), **8:** 21.
4. Bohuon, C., Clin. Chim. Acta. (1962), **7:** 811-817.
5. Rice E.N., Lapara, C.Z., Clin. Chim. Acta. (1964) **10:** 369.

9. PERFORMANCE CHARACTERISTICS

Analytical performance:

a. Precision/Reproducibility:

Precision was evaluated consistent with C.L.S.I documents EP05-A3 'Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline- Third Edition'. Precision studies were performed by two operators on two RX **daytona plus** systems using control material.

For serum precision study unaltered human serum samples that were spiked with magnesium chloride or diluted producing five different levels ranging from 0.90-4.43 mg/dl.

Urine precision study used three levels of human urine supplemented with magnesium chloride. The three levels used ranged from 3.15-12.42 mg/dl. In addition the 'LIN' sample used consisted of a normal urine pool spiked up to an elevated level of 21.10 mg/dl using magnesium chloride.

Testing was conducted for two reagent lots of Magnesium, one lot on each RX **daytona plus** system, twice per day for 20 non-consecutive days. Two replicates per run were performed for each sample. The assay was calibrated on the first day of the study and no assay re-calibrations were required throughout the duration of the study. The results of Serum Lot 2 and Urine lot 1, which are representative of both lots of reagent, are summarized in the following table.

Table 2: Precision Summary- Serum Lot 2

Serum Lot 2			Mean	Within Run		Total	
Method	**Product**	**N**	**(mg/dl)**	**SD**	**CV**	**SD**	**CV**
Magnesium	QC1 (Control 2, lot 1093UN)	80	2.36	0.06	2.4	0.07	2.8
Magnesium	QC2 (Calibrator, lot 844UE)	80	4.36	0.12	2.7	0.14	3.3
Magnesium	QC3 (Control 3, lot 845 UE)	80	4.23	0.12	2.8	0.12	2.8
Magnesium	Serum Pool 1	80	0.90	0.02	2.3	0.04	4.1
Magnesium	Serum Pool 2	80	1.17	0.03	3.0	0.05	4.1
Magnesium	Serum Pool 3	80	2.54	0.04	1.8	0.07	2.8
Magnesium	Serum Pool 4	80	3.64	0.06	1.7	0.10	2.8
Magnesium	Serum Pool 5	80	4.43	0.06	1.4	0.10	2.3

Table 3: Precision Summary- Urine Lot 1

Urine Lot 1			Mean	Within Run		Total	
Method	**Product**	**N**	**(mg/dl)**	**SD**	**CV**	**SD**	**CV**
Magnesium	QC1	80	4.58	0.13	2.9	0.23	5.1
Magnesium	QC2	80	7.68	0.20	2.6	0.32	4.2
Magnesium	Urine Pool 1	80	3.15	0.10	3.3	0.18	5.8
Magnesium	Urine Pool 2	80	9.05	0.19	2.1	0.42	4.7
Magnesium	Urine Pool 3	80	12.42	0.23	1.8	0.73	5.9
Magnesium	LIN	80	21.10	0.27	1.3	1.23	5.8

b. Linearity/assay reportable range:

Linearity studies have been carried out in accordance with C.L.S.I. standard EP6-A- 'Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline'. Linearity studies were performed at 11 levels to determine the analytical range of an assay - that is the range where the reported result is a linear function to the analyte concentration (or where deviation from linearity is less than 5%).

The linearity samples were prepared at 11 levels. The sponsor set a range for analyte concentration from approximately 0.70 mg/dl (serum) and 0.95 mg/dl (urine) up to high concentrations of approximately 5 mg/dl (serum) and 25 mg/dl (urine) using low and high serum pools. The low and high pools were mixed to make nine intermediate levels. Each level was run in replicates of five on two lots of Magnesium reagent on one RX **daytona plus** system. The observed values were compared to the expected values; the linear regression correlation between the expected values and the observed values are summarized in the following table:

Table 4: Linearity Summary including Regression equation and correlation co-efficient.

Analyte Tested	Magnesium (mg/dl) (Serum)
Linear Regression	Y = 0.96x+0.08
r	0.999

Analyte Tested	Magnesium (mg/dl) (Urine)
Linear Regression	Y=0.97x+0.32
r	0.998

The reportable range of the assay is 0.74-4.95 mg/dl in serum and 1.01-23.82 mg/dl in urine.
The low end of the range is based on the LOQ and the high end of the reportable assay range is based on the linearity.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Refer to K053153 Randox Calibration Serum Level 3 and K942458 Randox Assayed Multi-sera Level 2 and Level 3.

The Randox Calibration Serum Level 3 is traceable to Magnesium reference material NIST 909b.

d. Detection limit:

Sensitivity studies have been carried out in accordance with C.L.S.I. guideline EP17-A2- 'Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - - Second Edition'. A Limit of Blank (L.o.B), a Limit of Detection (L.o.D) and a Limit of Quantification (L.o.Q) were performed on two lots of reagents tested by two operators on one RX **daytona plus** system. The results of lot 1 for both serum and urine, which are representative of both lots, are summarized below.

The Limit of Detection (LoD) for magnesium on the RX **daytona plus** is 0.39 mg/dl for serum and 0.68mg/dl for urine, based on 240 determinations, with 4 low level samples.

The Limit of Blank (LoB) is 0.28 mg/dl for serum and 0.44 mg/dl for urine.

The Limit of Quantitation (LoQ) is 0.55mg/dl for serum and 0.95mg/dl for urine, as determined by the lowest concentration detected with a %CV of ≤20%.

e. Analytical Specificity:

Interference studies have been carried out in accordance with C.L.S.I. guideline EP07-A2- 'Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition'. The effects of potential interferents were determined by calculating the mean value of the spiked interferent with the corresponding control solution. The spiked sample results were compared to control samples prepared without the potential interferents.

Acceptance Criteria: % of Control ± 10%

Serum Interference
The following analytes were tested up to the levels indicated at magnesium concentrations of 3.89 mg/dl and 6.32 mg/dl and found not to interfere:

Hemoglobin	No significant interference up to 1000mg/dl.
Total Bilirubin	No significant interference up to 60mg/dl.
Conjugate Bilirubin	No significant interference up to 60mg/dl.
Triglycerides	No significant interference up to 2000mg/dl.
Intralipid®	No significant interference up to 500mg/dl.
Ascorbic Acid	No significant interference up to 6mg/dl.

Urine Interference
The following analytes were tested up to the levels indicated at magnesium concentrations of 4.87mg/dl and 24.33mg/dl and found not to interfere:

	4.87mg/dl	**24.33mg/dl**
Direct Bilirubin	60mg/dl	60mg/dl
Total Bilirubin	60mg/dl	60mg/dl
Haemoglobin	250mg/dl	250mg/dl
G-Globulin	500mg/dl	500mg/dl
Glucose	2000mg/dl	2000mg/dl
Ascorbic Acid	150mg/dl	200mg/dl
H.S.A	500mg/dl	500mg/dl
Oxalate	100mg/dl	100mg/dl
Ethanol	1000mg/dl	1000mg/dl
Boric Acid	750mg/dl	1000mg/dl
Sodium Chloride	4000mg/dl	4000mg/dl
Sodium Fluoride	25mg/dl	25mg/dl

f. Method comparison with predicate device:

Correlation studies were carried out in accordance with C.L.S.I. guideline EP09-A3- 'Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition'. 108 serum patient samples spanning the range 0.80-4.54 mg/dl were tested by two operators on two lots of Randox RX **daytona plus** magnesium (Mg) reagent on one RX **daytona plus** analyzer and on two lots of Siemens Magnesium (MG) reagent on one Advia 1800 system across 3 working days with each sample tested in singlicate. The test method was compared to the predicate device and the following linear regression equation was obtained:

Y = 0.994x+0.050
Correlation coefficient of r = 0.992

108 urine patient samples spanning the range 1.15 to 23.12 mg/dL were tested by two operators on two lots of Randox RX **daytona plus** magnesium (Mg) reagent on one RX **daytona plus** analyzer and two lots of Siemens Magnesium (MG) reagent on one Advia 1800 sytem across three working days with each sample being tested in singlicate. The test method was compared to the predicate device and the following linear regression equation was obtained:

Y = 0.990x +0.067
Correlation coefficient of r = 0.999

g. Matrix comparison:

Matrix method comparisons for the Randox RX **daytona plus** magnesium (Mg) assay were tested by one operator on one RX **daytona plus** system and were assessed for two lots of magnesium reagents. Both serum and lithium heparin plasma were tested to determine whether method accuracy with plasma specimens are equivalent to serum results and that lithium heparin plasma does not interfere with either the method or the system.

Magnesium matrix comparison on the RX **daytona plus** (Lithium Heparin)

Patient samples were drawn in matched pairs – one sample serum (x) and the second sample lithium heparin plasma (y). A minimum of 42 matched patient sample pairs were analyzed spanning the range 0.75 to 4.13 mg/dl and the following linear regression equation was obtained:

Y = 0.96x+0.09
Correlation coefficient of r = 0.992

Expected values/Reference range:

Referenced from literature

Table 5: Reference Ranges

Analyte	Serum	Urine (24hr)
Magnesium [6,7]	Adult 1.70 - 2.70 mg/dL	Adult 72.9-121.5 mg/day

6. Lau, K-K., Yu, W-C., Chu, C-M., Lau, S-T., Sheng, B. and Yuen, K-Y. Possible Central Nervous System Infection by SARS Caronavirus. Emerging Infectious Diseases. Vol 10 No 2. (2004) p342-344.
7. Wu AH. Tietz Clinical Guide to Laboratory Tests, 4th ed. Philadelphia, PA: WB Saunders; 2006: 706-8

10. CONCLUSION

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