DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 6, 2015

RANDOX LABORATORIES LIMITED
PAULINE ARMSTRONG
QA/RA MANAGER
55 DIAMOND ROAD
CRUMLIN BT29 4QY, GREAT BRITAIN

Re: K150819
Trade/Device Name: Triglycerides (TRIGS)
Regulation Number: 21 CFR 862.1705
Regulation Name: Triglyceride test system
Regulatory Class: Class I, meets the limitation of exemption 21 CFR §862.9(c)(4)
Product Code: CDT
Dated: June 18, 2015
Received: June 22, 2015

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,

Courtney H. Lias -S

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.*

51O(k) Number *(if known)*

K150819

Device Name
Triglycerides (TRIGS)

Indications for Use *(Describe)*

For the quantitative in vitro determination of Triglycerides in serum. Triglyceride measurements are used in the diagnosis and treatment of diseases involving lipid metabolism and various endocrine disorders e.g Diabetes mellitus, nephrosis and liver obstruction

This in vitro diagnostic device is intended 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)*

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

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510(K) SUMMARY, TRIGLYCERIDES ASSAY

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: July 9, 2015

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

510k No: K150819

Device Proprietary Name: Triglycerides (TRIGS)

Common Name: Triglycerides

Purpose for Submission: New Device

Product Code	Regulation Name	Classification	Regulation Section	Panel
CDT	Triglycerides test system	I, meets the limitations to exemptions 21 CFR §862.9 (c)(4)	21 CFR 862.1705	Clinical Chemistry (75)

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

Predicate Device Proprietary Name:
Randox Laboratories Ltd, Triglycerides reagent

510 (k) Number: K923508

5. INTENDED USE

For the quantitative in vitro determination of Triglycerides in serum. Triglyceride measurements are used in the diagnosis and treatment of diseases involving lipid metabolism and various endocrine disorders e.g Diabetes mellitus, nephrosis and liver obstruction

This in vitro diagnostic device is intended for prescription use only.

6. DEVICE DESCRIPTION

The Randox Triglycerides kit assay consists of ready to use reagent solutions.

CATALOGUE NUMBER: TR8332

R1. Enzyme Reagent 4 x 20 ml

REAGENT COMPOSITION

Contents	Initial Concentrations
R1. Enzyme Reagent	
Pipes buffer	38.7 mmol/L, pH 7.5
4-chloro-phenol	3.4 mmol/L
Magnesium ions	16.9 mmol/L
4- aminophenazone	0.25 mmol/L
ATP	1.2 mmol/L
Lipases	≥ 10 u/mL
Glycerol kinase	≥ 0.4 u/mL
Glycerol-3-phosphate oxidase	≥ 1.5 u/mL
Peroxidase	≥ 0.5 u/mL
Sodium azide	0.05%

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Assayed Multisera Level 2 (Cat. No. HN 1530) and
Level 3 (Cat. No. HE 1532); 510(k) # k942458
Randox Calibration Serum Level 3 (Cat. No. CAL 2351); 510(k) # k053153
RX series Saline (Cat. No. SA 8396)

7. PREDICATE DEVICE COMPARISON TABLE

Table 1 **Comparison of Triglycerides test system for the RX Daytona plus to predicate device**

CHARACTERISTICS	Randox Triglycerides Assay for RX daytona plus *(New Device)*	*Randox Triglyceride Assay (K923508) (Predicate Device)*
Similarities		
INTENDED USE	For the quantitative in vitro determination of Triglycerides in serum. Triglyceride measurements are used in the diagnosis and treatment of diseases involving lipid metabolism and various endocrine disorders e.g Diabetes mellitus, nephrosis and liver obstruction	Same
ASSAY PROTOCOL	Colorimetric Method	Same
STORAGE (UNOPENED)	Reagents are stable up to the expiry date when stored unopened at +2 to +8°C	Same
CONTROL FREQUENCY	Randox assayed human multisera Level 2 & 3 Two levels of control should be assayed at least once a day	Same
CALIBRATION FREQUENCY	Every 28 days, with a change of reagent lot or as indicated by quality control procedures.	Same

Differences		
REAGENT COMPOSITION	**R1. Enzyme Reagent** Pipes buffer 38.7 mmol/L, pH 7.5 4-chloro-phenol 3.4 mmol/L Magnesium ions 16.9 mmol/L 4- aminophenazone 0.25 mmol/L ATP 1.2 mmol/L Lipases ≥ 10 u/mL Glycerol kinase ≥ 0.4 u/mL Glycerol-3-phosphate oxidase ≥ 1.5 u/mL Peroxidase ≥ 0.5 u/mL Sodium azide 0.05%	**R1a. Buffer** Pipes Buffer 40 mmol/l, pH 7.5 4-chloro-phenol 5.0 mmol/l Magnesium-ions 5.0 mmol/l **R1b. Enzyme Reagent** 4-aminophenazone 0.4 mmol/l ATP 1.0 mmol/l Lipases ≥150 U/ml Glycerol-kinase ≥ 0.4 U/ml Glycerol-3-phosphate oxidase ≥ 1.5 U/ml Peroxidase ≥ 0.5 U/ml
TEST RANGE	12.4 – 1000mg/dl	11.5 – 1133mg/dl
SAMPLE TYPE	Serum	Serum, heparinized plasma and EDTA plasma samples are suitable.

8. TEST PRINCIPLE

The Triglycerides is determined after enzymatic hydrolysis and oxidation. The indicator quinoneimine is formed from hydrogen peroxide and 4-aminoantipyrine in the presence of phenol and peroxidase and read at 510nm.

$$\text{Triglycerides} + H_20 \xrightarrow{\text{Lipases}} \text{Glycerol} + \text{Fatty acids}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow{\text{GK}} \text{Glycerol-3-phosphate} + \text{ADP}$$

$$\text{Glycerol-3-phosphate} + 0_2 \xrightarrow{\text{GPO}} \text{Dihydroxyacetone} + \text{Phosphate} + H_20_2$$

$$2H_20 + \text{4-aminophenazone} + \text{4 chlorophenol} \xrightarrow{\text{POD}} \text{Quinoneimine} + HCl + 4\ H_20$$

9. PERFORMANCE CHARACTERISTICS

Analytical performance:

a. Precision/Reproducibility:
Precision was evaluated consistent with C.L.S.I documents EP5-A2
Precision studies were performed by two operators on two RX Daytona plus systems using serum based control material and unaltered human serum samples that were spiked with triglycerides concentrations or diluted to achieve concentrations based on established ranges <150 mg/dl normal triglycerides level ; 150 – 199 mg/dl borderline high triglycerides level; 200 – 499 mg/dl high triglycerides level and ≥ 500 mg/dl very high triglycerides level. Testing was conducted for two reagent lots of triglycerides, 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. No assay re-calibrations were required throughout the duration of the study. The results are summarized in the following tables.

Table 2 **Precision Summary**

System: RX Daytona Plus			Within Run		Among Run		Among Day		Total	
Method Lot 1	**Product**	**MEAN (mg/dl)**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**
Triglycerides	Sensitivity Pool	13.3	0.88	8.0	0.00	2.8	1.77	10.3	4.42	13.4
Triglycerides	Serum Pool 1	96.4	1.77	1.9	0.88	0.6	0.88	0.8	1.77	2.1
Triglycerides	QC 1	96.5	1.77	1.8	0.88	1.0	0.88	1.0	1.77	2.3
Triglycerides	Patient Pool 2	104	1.77	2.1	0.88	1.1	0.88	1.0	2.65	2.5
Triglycerides	Patient Pool 1	117	2.65	2.3	0.88	0.6	0.88	0.6	2.65	2.5
Triglycerides	Serum Pool 2	237	4.42	1.9	0.00	0.0	1.77	0.8	7.08	2.1
Triglycerides	CAL	240	3.54	1.5	3.54	1.3	0.00	0.0	4.42	2.0
Triglycerides	QC 2	259	3.54	1.3	0.88	0.2	1.77	0.7	3.54	1.5
Triglycerides	Serum Pool 3	326	4.42	1.4	1.77	0.5	1.77	0.5	4.42	1.6

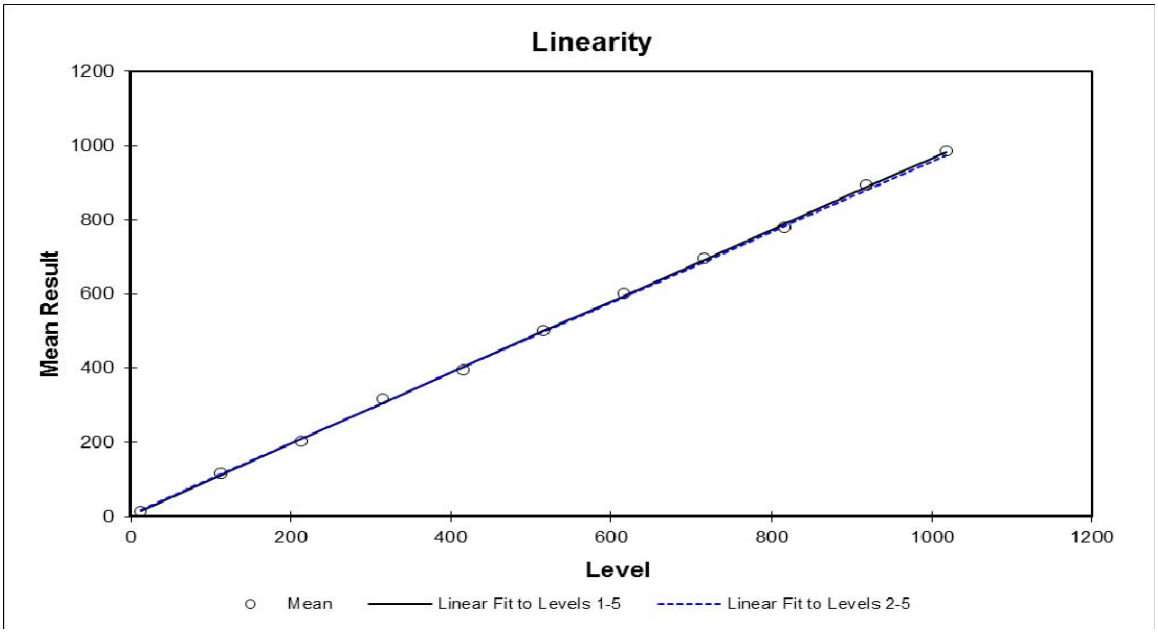
System: RX Daytona Plus			Within Run		Among Run		Among Day		Total	
Method Lot 2	**Product**	**MEAN (mg/dl)**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**
Triglycerides	Sensitivity Pool	17.7	0.88	4.6	0.88	6.1	4.42	8.7	1.77	11.6
Triglycerides	801UN QC 2	97.3	2.65	2.5	0.00	0.5	1.77	2.0	3.54	3.2
Triglycerides	Serum Pool 1	111	2.65	2.2	1.77	1.8	2.65	2.2	3.54	3.6
Triglycerides	832UE CAL	235	5.31	2.4	0.00	0.0	4.42	1.8	7.08	3.0
Triglycerides	Serum Pool 2	252	3.54	1.6	4.42	1.6	3.54	1.3	6.19	2.6
Triglycerides	587UE QC 3	265	4.42	1.7	2.65	1.0	4.42	1.6	6.19	2.5
Triglycerides	Serum Pool 3	326	7.08	2.1	7.08	2.1	7.08	2.1	12.4	3.7
Triglycerides	Serum Pool 4	514	11.5	2.2	0.00	0.0	7.96	1.6	14.2	2.8

b. Linearity/assay reportable range:

Linearity studies have been carried out in accordance with C.L.S.I. standard EP6-A. 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 from 12.4 mg/dl analyte concentration up to a high concentration approximately 1000mg/dl 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 Triglycerides reagent on one RX Daytona plus system. The observed values were compared to the expected values; the results are summarized in the following table:

Table 3 **Linearity Summary including Regression equation and correlation co-efficient.**



Slope	0.96
Intercept	3.30
r	1.000

Analyte	Linearity	Reportable Range
Triglycerides	1000 mg/dl	12.4 – 1000 mg/dl

The low end of the reportable assay range is based on the Limit of Quantitation. The high end of the reportable assay range is based on the linearity.

The Rx Daytona Plus analyzer has an auto-dilution feature that is automatically activated when measuring samples >1000 mg/dL, which are diluted and re-measured to obtain values within the measuring range.

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

Refer to K053153 Calibrator and K942458 Control for Triglycerides.

Randox Calibration Serum Level 3 is traceable to Triglycerides reference method ID-GC/MS.

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 were performed on two lots of reagents tested by two operators on one RX Daytona Plus system.

The Limit of Detection (LoD) for Triglycerides on the RX Daytona Plus is 3.96 mg/dl based on 240 determinations, with 4 low level samples.

The Limit of Blank (LoB) is 2.65 mg/dl.

The Limit of Quantitation (LoQ) is 12.4 mg/dl as determined by the lowest concentration at which precision is still met.

e. Analytical Specificity:

Interference studies have been carried out in accordance with C.L.S.I. guideline EP7-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.

<u>Acceptance Criteria</u>:
The criteria for no significant interference is recovery within ±10% of the initial value of Triglycerides concentration of 150mg/dL and 496mg/dL

Haemoglobin	No significant interference up to 750mg/dL
Total Bilirubin	No significant interference up to 60mg/dL

Conjugate Bilirubin	No significant interference up to 60mg/dL
Ascorbic Acid	No significant interference up to 3.0mg/dL

f. Method comparison with predicate device:

Correlation studies were carried out in accordance with C.L.S.I. guideline EP9-A2 'Method Comparison and Bias Estimation Using Patient Samples: Approved Guideline – Second Edition'.

109 serum patient samples spanning the range 14.2 to 986 mg/dl were tested by two operators on two lots of Triglycerides reagent on one RX Daytona plus analyzer and the predicate device tested on one RX Imola 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 = 0.97x + 1.22
Correlation coefficient of r = 0.999

Expected values/Reference range:

The NCEP (American National Cholesterol Education Program) has established the following classification for triglyceride levels according to the risk of developing coronary heart diseases:

Table 4 **Reference Ranges**

Analyte	**Expected Values**
Triglycerides [1]	Normal < 150 mg/dl Borderline-high 150 – 199 mg/dl High 200 – 499 mg/dl Very High ≥ 500 mg/dl

1. ATP III Guidelines At-A-Glance Quick Desk Reference, National Cholesterol Education
Program, National Institute of Health Publication No. 01-3305, May 2001.

10. CONCLUSION

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