K122126

AUG 14 2012

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: Randox Laboratories Limited

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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: k122126

Device Proprietary Name: Randox Direct LDL/HDL Cholesterol Calibrator

Common Name: Direct LDL/HDL Cholesterol Calibrator

Purpose for Submission: New Device

Regulatory Classification: Primary Calibrator Class II

Panel: Clinical Chemistry

Product Code: JIS

21 CFR Number: 21 CFR 862.1150

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

Predicate Device Proprietary Name: Teco Diagnostics Direct HDL/LDL Cholesterol Calibrator

510 (k) Number: k050823

5. INTENDED USE

The Randox Direct LDL/HDL Cholesterol Calibrator is intended for in vitro diagnostic use in the calibration of Randox HDL and LDL cholesterol methods. This in vitro diagnostic device is intended for prescription use only and can only be used by professionals.

6. DEVICE DESCRIPTION

The Randox Direct LDL/HDL Cholesterol Calibrator is supplied in a kit containing 3x1mls vials. The calibrator contains the analytes LDL and HDL.

The base matrix used for the manufacture of Randox Direct LDL/HDL Cholesterol Calibrator is Human Serum. The calibrator contains lipoproteins from the various lipoprotein classes including high density lipoproteins.

7. PREDICATE DEVICE COMPARISON TABLE

CHARACTERISTICS	RANDOX DIRECT LDL/HDL CHOLESTEROL CALIBRATOR	TECO DIAGNOSTICS DIRECT HDL/LDL CHOLESTEROL CALIBRATOR
INTENDED USE	The Randox Direct LDL/HDL Cholesterol Calibrator is intended for in vitro diagnostic use in the calibration of Randox HDL and LDL Cholesterol methods. This in vitro diagnostic device is intended for prescription use only and can only be used by professionals.	The Teco Diagnostics Direct HDL/LDL Cholesterol Calibrator is intended for the calibration of Teco Diagnostics' direct HDL and LDL Cholesterol Reagent set in serum or plasma. For in vitro diagnostic use only.
SIZE	Randox Direct LDL/HDL Cholesterol calibrator 3x1ml	Teco Diagnostics Direct HDL/LDL Cholesterol Calibrator 3mls
FORMAT	Lyophilized serum calibrator	Lyophilized serum calibrator
MATRIX	Human Serum. The calibrator contains lipoproteins from the various lipoprotein classes including high density lipoproteins	Human Serum. The calibrator contains lipoproteins from the various lipoprotein classes including high density lipoproteins
STORAGE (unopened)	Stable to the expiry date printed on the product label when stored between +2°C and +8°C	Stable to the expiry date printed on the product label when stored between +2°C and +8°C
STORAGE (Opened)	Once reconstituted, the components in the calibrator are stable for 5 days at +2°C to +8°C	Once reconstituted, the components in the calibrator are stable for 21 days at +2°C to +8°C
ANALYTES	Direct LDL Direct HDL	Direct LDL Direct HDL

8. SUMMARY OF STABILITY STUDIES

Unopened Calibrator is stable until the expiry date printed on the product label when stored between +2°C and +8°C. Once reconstituted the components are stable for 5 days at +2°C and +8°C and 1 month at -20°C when frozen once. After use, any residual product should NOT be returned to the original vial.

9. SUMMARY OF VALUE ASSIGNMENT

The assigned values for the direct LDL/HDL Cholesterol Calibrator are established on multiple analysers with reference to a master lot.

Analyte	System	Target	
		mmol/l	mg/dl
Direct HDL	Abbott Architect c8000	1.77	68.3
	Beckman Coulter AU640	1.73	66.8
	Hitachi 717	1.67	64.5
	Hitachi 911	1.65	63.7
	Randox RX Daytona	1.73	66.8
	Randox Rx Imola	1.65	63.7
	Siemens Advia 1650	1.7	65.6
Direct LDL	Beckman Coulter AU640	3.16	122
	Hitachi 717	3.01	116
	Hitachi 911	3.03	117
	Randox RX Daytona	3.11	120
	Randox Rx Imola	3.12	120
	Siemens Advia 1650	3.09	119

10. TRACEABILITY

ANALYTE	SUPPLIER	PRODUCT NUMBER	ORIGIN	SOURCE
Direct HDL	Creative Labs	361-10	Human	Plasma
Direct LDL	Creative Labs	360-10	Human	Plasma

11. 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
Silver Spring, MD 20993

Randox Laboratories Ltd.
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55 Diamond Road
Crumlin, County Antrim BT29 4QY
United Kingdom

AUG 14 2012

Re: k122126
Trade Name: Randox Direct LDL/HDL Cholesterol Calibrator
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIS
Dated: July 18, 2012
Received: July 18, 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): k122126

Device Name: Direct LDL/HDL Cholesterol Calibrator

Indication for Use:

The Randox Direct LDL/HDL Cholesterol Calibrator is intended for in vitro diagnostic use in the calibration of Randox HDL and LDL Cholesterol methods.

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

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