K131999

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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JUL 26 2013

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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: HbA1c Control Levels 1 and 2

Common Name: HbA1c Controls Levels 1 and 2

Purpose for Submission: New Device

Regulatory Classification: Single Specified Analyte Controls (Assayed and Unassayed) Class I reserved

Panel: Clinical Chemistry

Product Code: JJX

21 CFR Number: 21 CFR 862.1660

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

Predicate Device Proprietary Name:
Roche PreciControl HbA1c norm and PreciControl HbA1c path

510 (k) Number: K103099

5. INTENDED USE

The HbA1c Controls Level 1 and 2 are intended for *in vitro* diagnostic use as quality control material for use to verify the performance of laboratory testing procedures of HbA1c on clinical chemistry systems. This device is intended for prescription use only.

6. DEVICE DESCRIPTION

HbA1c Controls are manufactured at two levels, Level 1 and Level 2.
Each control is prepared from haemolysed human blood with added constituents of human origin, chemicals, stabilizers and preservatives. They are supplied in lyophilised form in 2x0.5ml vials and require reconstitution with 0.5ml of distilled water.

7. PREDICATE DEVICE COMPARISON TABLE

COMPARISON OF RANDOX HbA1c CONTROLS LEVEL 1 AND 2 WITH THE PREDICATE DEVICE

CHARACTERISTICS	RANDOX HbA1c CONTROLS LEVEL 1 AND LEVEL 2	ROCHE PRECICONTROL HbA1c norm PRECICONTROL HbA1c path K103099
INTENDED USE	For use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets	Same
SIZE	0.5ml	1ml
FORMAT	Lyophilised	Liquid
REAGENT COMPOSITION	Matrix The controls are based on haemolysed human blood Components HbA1c is isolated from human blood	Matrix Same Components HbA1c is isolated from a normal population then glycated in vitro
STABILITY	Unopened 2-8°C until expiration Stability after opening 2-8°C for 1 month	Unopened Same Stability after opening 2-8°C for 28 days (-15)-(-25)°C for 12 weeks (freeze only once)

8. SUMMARY OF STABILITY STUDIES

Opened: Store refrigerated (+2°C to +8°C). Reconstituted HbA1c is stable for 1 month at +2°C to +8°C if kept capped in the original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should not be returned to the original vial.
Unopened: Store refrigerated (+2°C to +8°C). Stable to the expiration date printed on individual vials.

9. SUMMARY OF VALUE ASSIGNMENT

Value assignment is used to calculate a target value for the HbA1c Controls level 1 and 2 on various clinical chemistry analysers. A target value is calculated for each new lot of controls by taking the mean of at least two replicates on each clinical chemistry analyser. The NGSP aligned values are taken from external laboratories, a consensus mean calculated which is then converted to IFCC values using the following master formula:

IFCC = (NGSP - 2.15) x 10.929

The acceptance criteria states the precision measured by the CV should be less than or equal to 10% for each clinical chemistry analyser. An assigned target value is applied and a +/-20% range applied.

10. TRACEABILITY

NGSP aligned values are obtained from external laboratories using NGSP certified methods. IFCC values are calculated from the NGSP values using the master equation:

IFCC = (NGSP – 2.15) x 10.929

ANALYTE	Reference Material	Assignment Method	ORIGIN
HbA1c	Traceable to IFCC by master equation	Consensus Mean	Human Haemolysed Blood

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
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 26, 2013

Randox Laboratories
C/O Pauline Armstrong
55 Diamond Road
Crumlin, Co Antim, BT294QY, UK

Re: K131999
Trade/Device Name: HbA1c Controls Level 1
HbA1c Controls Level 2
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: II
Product Code: JJX
Dated: June 26, 2013
Received: June 28, 2013

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. 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,

Courtney H. Lias, Ph.D.

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): k131999

Device Name: HbA1c Control Level 1 and HbA1c Control Level 2

Indication for Use:

The HbA1c Controls Level 1 and 2 are intended for *in vitro* diagnostic use as quality control material for use to verify the performance of laboratory testing procedures of HbA1c on clinical chemistry systems.

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

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 Diagnostics and Radiological Health (OIR)

Katherine Serrano -S

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

510(k) k131999