JUN 20 2012

K121588

510(k) Summary

Safety and Effectiveness as Required by 21 CFR 807.92

Manufacturer and Submitter

Name: Randox Laboratories Limited

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

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Fax: +44 (0) 28 9445 2912
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Device Name

Trade Names: Randox Cystatin C Level 2 and Randox Cystatin C Level 3.

Common Names: Cystatin C Level 2 and Randox Cystatin C Level 3.

Classification: Single (Specified) Analyte Controls (Assayed and Unassayed)

Product Code: JJX

Date of Summary Preparation

11TH May 2012

Predicate Devices

DakoCytomation Cystatin C Control Set, K041627

Device Description

Randox Cystatin C Controls are manufactured at two levels, Level 2 and Level 3. They are single analyte controls derived from human serum. The analyte concentrations in each control have been reviewed by a panel of experts to ensure that the concentrations are clinically relevant for use in routine hospital laboratories.

Intended Use

Randox Cystatin C Controls Levels 2 and 3 are intended for in vitro diagnostic use as assayed quality control material for monitoring the precision and accuracy of the quantitative determination of human Cystatin C by immunoturbidimetric Assays.

Similarities to the Predicate Device

- The Randox Cystatin C Controls are bi-level materials intended for in vitro diagnostic use in quality control.
- They have a human serum matrix and are preserved with sodium azide
- They are provided in liquid form and are ready to use
- They are stable up to the expiry date when capped and stored at +2 to +8°C.

Stability

OPENED: The Cystatin C Controls are stable for 30 days when capped in the original container at +2 to +8°C in the absence of contamination.
UNOPENED: The Cystatin C Controls are supplied ready to use and are stable up to the expiry date when capped and stored at +2 to +8°C in the absence of contamination.

Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

JUN 20 2012

Randox Laboratories Limited
c/o Pauline Armstrong
55 Diamond Road, Crumlin,
County Antrim, BT29 4QY,
United Kingdom

Re: k121588
Trade Name: Cystatin C Control Level 2 and Cystatin C Control Level 3
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Codes: JJX
Dated: May 31, 2012
Received: May 31, 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):

Device Name: Cystatin C Controls Levels 2 and 3

Indication for Use:

The Randox Cystatin C Controls Level 2 and Level 3 are intended for use as assayed quality control material for monitoring the precision and accuracy of the quantitative determination of human Cystatin C by immunoturbidimetric Assays.

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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