



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

APR 08 2011

Radox Laboratories, LTD  
c/o Dr. Pauline Armstrong  
Regulatory Affairs  
55 Diamond Road  
Crumlin, County Antrim,  
United Kingdom BT29 4QY

Re: k092269  
Trade Name: Radox Cannabinoids Assay, Cannabinoid Calibrator Set, Cannabinoid Controls, Level 1 & 2  
Regulation Number: 21 CFR 862.3870  
Regulation Name: Cannabinoid Test System.  
Regulatory Class: Class II  
Product Codes: LDJ, JIT, JJX  
Dated: March 29, 2011  
Received: March 31, 2011

Dear Dr. 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.

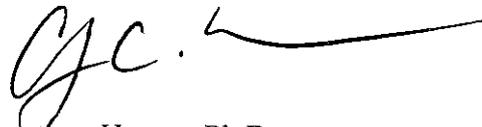
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 Parts 801 and 809), 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 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/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CH', with a long horizontal line extending to the right.

Courtney Harper, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): k092269  
Device Name: CANNABINOIDS ASSAY, CALIBRATOR SET AND CONTROLS  
LEVEL 1 & 2  
Indication For Use:

### Randox Cannabinoids Assay

The Randox Laboratories Ltd. Cannabinoid Assay is an in vitro diagnostic test for the detection of 11-nor- $\Delta^9$ -THC-9-COOH (THC) in human urine on the Rx imola and Rx Daytona. The cut off for 11-nor- $\Delta^9$ -THC-9-COOH (THC) is 50ng/ml, This in vitro diagnostic device is intended for prescription use only.

The semi-quantitative mode is for purposes of

- (1) enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GCMS
- or
- (2) permitting laboratories to establish quality control procedures.

**This assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatograph/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.**

### Randox Cannabinoid Calibrator Set

The Randox Cannabinoid Calibrator Set consists of liquid calibrators containing 11-nor- $\Delta^9$ -THC-9-COOH (THC). There are 5 levels of calibrator. They have been developed for use in the calibration of THC assays on the **IXdaytona™** and **IXimola™** analysers. This in vitro diagnostic device is intended for prescription use only.

### Randox Cannabinoid Controls, Level 1 & 2

The Randox Cannabinoid Controls, level 1 and 2 are liquid controls containing 11-nor- $\Delta^9$ -THC-9-COOH (THC). There are 2 levels of controls. They have been developed for use in the quality control of the THC assay on the **IXdaytona™** and **IXimola™** analysers. 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 Diagnostic Device Evaluation and Safety (OIVD)

  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K092269