DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 27 2005

Dr. Pauline Armstrong
Regulatory Affairs
Randox Laboratories Ltd.
Biochemical Manufacturers
55 Diamond Road
Crumlin, Co. Antrim
United Kingdom, BT29 4QY

Re: k043071
Trade/Device Name: evidence® Phencyclidine Assay
evidence® Drugs of Abuse Calibrators
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: LCM, DKB
Dated: November 5 2004
Received: November 8, 2004

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~UNKNOWN~~ K043071

Device Name: evidence® PHENCYCLIDINE ASSAY AND evidence® DRUGS OF ABUSE CALIBRATORS

Indications For Use:

The evidence® Phencyclidine test has been designed for use only on the evidence® analyser for qualitative detection of phencyclidine in urine, using a cut-off concentration of 25 ng/ml. Qualitative results obtained can be utilised in the diagnosis and treatment of phencyclidine use or overdose.

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

The Phencyclidine Assay must only be used by suitably qualified laboratory personnel under appropriate laboratory conditions.

The evidence® Drugs of Abuse Calibrators.

The evidence® Drugs of Abuse Calibrators are liquid Calibrators containing benzoylecgonine, amphetamine, methamphetamine, methadone, opiates and phencyclidine. There are 9 levels of calibrator. They have been developed for use in calibration of the evidence® system.

The evidence® Drugs of Abuse Calibrators must only be used by suitably qualified laboratory personnel under appropriate laboratory conditions.

✓

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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

510(k) K043071