



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 23 2003

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

Re: k030360

Trade/Device Name: Cocaine Metabolite Assay, Drugs of Abuse Calibrators & Evidence™
Automated Immunoassay Analyzer

Regulation Number: 21 CFR 862.3250

Regulation Name: Cocaine and cocaine metabolite test system

Regulatory Class: Class II

Product Code: DIO; JJE; DLJ

Dated: November 3, 2003

Received: November 5, 2003

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.

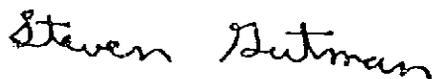
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

Page 2 --

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 (301) 594-3084. 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/dsma/dsmamain.html>.

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known)

K030360

Device Name

**COCAINE METABOLITE ASSAY,
DRUGS OF ABUSE CALIBRATORS &
EVIDENCE™ AUTOMATED IMMUNOASSAY ANALYSER**

Indications For Use:

Cocaine Metabolite Assay

The Randox Laboratories Limited Cocaine Metabolite Assay is an *in vitro* diagnostic test for the qualitative determination of the major metabolite of cocaine, benzoylecgonine (BZG), in human urine. This is a competitive immunoassay. A cut-off of 300ng/ml benzoylecgonine has been established in line with SAMHSA recommendations.

This assay is for use only on the automated Evidence™ Analyser.

Note: This test provides only a preliminary analytical result. A more specific alternative chemical method must be used to obtain a confirmed analytical result.

Gas Chromatography / Mass Spectrophotometry (GC/MS) is the preferred confirmatory method.

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

Drugs of Abuse Calibrators

The Randox Laboratories Limited Drugs of Abuse Calibrators are liquid calibrators containing benzoylecgonine. There are 9 levels of calibrator.

They have been developed for use in calibration of the Evidence™ system.

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

Evidence™ Automated Immunoassay Analyser

Evidence™ is an automated immunoassay analyser with dedicated software. It is for use with the Randox Evidence Cocaine Assay.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional format 1-2-96)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K030360