Randox Laboratories Limited
Karena Shaw
Regulatory Affairs Manager
55 Diamond Road
Crumlin, Co. Antrim BT29 4Qy
United Kingdom

Re: K220451
Trade/Device Name: Evidence MultiSTAT DOA Urine Multiplex, Evidence MultiSTAT
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG, DJC, JXM, DJR, JJE
Dated: March 7, 2023
Received: April 14, 2023

Dear Karena Shaw:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph A. Kotarek -S
Digitally signed by Joseph A. Kotarek -S
Date: 2023.10.05 14:19:18 -04'00'

Josepk Kotarek, Ph.D.
Toxicology Branch Chief
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
k220451

Device Name
Evidence MultiSTAT Urine DOA MultiPlex, Evidence MultiSTAT

Indications for Use *(Describe)*

The Evidence MultiSTAT DOA Urine MultiPlex is intended for use with the Evidence MultiSTAT. The Evidence MultiSTAT is an analyzer intended for the qualitative determination of parent drug molecule and metabolites of drugs in human urine at the associated cutoffs.

The Evidence MultiSTAT DOA Urine MultiPlex detects the following drugs at the following cut-offs:

| Analyte | Analyte in Cut Off Material | Cut-Off |
|---|---|---|
| Benzodiazepines I | Oxazepam | 200 ng/mL |
| Methamphetamine | S-(+)-Methamphetamine | 500 ng/mL |
| Noroxycodone | Noroxycodone | 100 ng/mL |
| Methadone | (±)-Methadone | 300 ng/mL |

The Evidence MultiSTAT DOA Urine MultiPlex provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and/or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) are the preferred confirmatory methods. Other chemical confirmation methods are available. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

For in vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

## 1. Substantial Equivalence as required by 21 CFR 807.92 Statement

This summary of the 510(k) substantial equivalence information is being submitted in accordance with the requirement of 21 CFR 807.92.

## 2. 510(k) Number Owner's Name and Address


Name: Randox Laboratories Limited

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

Telephone: +44 2894422413

Contact Person: Karena Shaw

E-mail: Karena.Shaw@randox.com


Date of Summary Preparation: 04 October 2023

## 3. Device Proprietary Names, Common Names, Purpose for Submission, Classification Name, Panel, Product Code and 21 CFR Number

510(k) Number: k220451

Device Proprietary Names: Evidence MultiSTAT Urine DOA MultiPlex, Evidence MultiSTAT

Common Names: Analyzer, Chemistry (Photometric, Discrete), For Clinical Use

Classification Names:

The Candidate Device Test System Regulatory Classification is Class II; the Classification Panel is Clinical Chemistry (75) and Clinical Toxicology (91). Regulatory information for the test system is detailed in table 1.

Table 1

| Product Code | Classification Name | Classification | Regulation Section | Panel |
|---|---|---|---|---|
| JJE | Analyzer, Chemistry (Photometric, Discrete), For Clinical Use | I | 21 CFR 862.2160 | Clinical Chemistry (75) |
| DJC | Methamphetamine Test System | II | 21 CFR 862.3610 | Clinical Toxicology (91) |
| JXM | Benzodiazepine Test System (Oxazepam) | II | 21 CFR 862.3170 | Clinical Toxicology (91) |
| DJR | Methadone Test System (Methadone) | II | 21 CFR 862.3620 | Clinical Toxicology (91) |
| DJG | Opiate Test System (Noroxycodone) | II | 21 CFR 862.3650 | Clinical Toxicology (91) |

## 4. Predicate Device Proprietary Names and 510(k) Numbers

The predicate device for the Evidence MultiSTAT System is the MEDTOX*Scan*® Reader (k091454) and is detailed in table 2.

Table 2: Similarities and Differences to Predicate Device

| Item | Candidate Device (k220451) Evidence MultiSTAT Urine DOA MultiPlex, Evidence MultiSTAT | Predicate Device (k091454) MEDTOXScan Reader |
|---|---|---|
| Indications for Use | Qualitative detection of drugs of abuse in urine | Same |
| Intended Use Setting | Prescription Use Only | Same |
| Methodology | Qualitative, Competitive Immunoassay | Qualitative immunochromatographic |
| Analytes | Methamphetamine, Noroxycodone | Same |
| Cutoffs (ng/mL) | Methamphetamine (500) Noroxycodone (100) | Same |

**4.1** The Evidence MultiSTAT analyzer is a benchtop fully automated Biochip Array System. It performs simultaneous detection of multiple analytes from a single sample. The core technology is the Randox Biochip, a solid-state device containing an array of discrete test regions containing immobilised antibodies specific to different Drugs of Abuse (DOA) compound classes. A competitive chemiluminescent immunoassay is used for the DOA assays with the drug in the specimen and drug labelled with horseradish peroxidase (HRP) being in direct competition for the antibody binding sites. Increased levels of drug in a specimen will lead to reduced binding of drug labelled with HRP and thus a reduction in chemiluminescence being emitted. The light signal generated from each of the test regions on the biochip is detected by a Charge Coupled Device (CCD) camera in the Evidence MultiSTAT system which, together with the analyzer software, is used to quantify the light output and produce meaningful results.

The immunoassay processes are performed automatically in a self-contained and sealed biochip cartridge, which holds the biochips, the reagents, wash buffer and other fluids required for the test to be conducted.

Evidence MultiSTAT assays employ a qualitative reporting method. Each test sample is assayed against the provided Cut Off material of known concentration, which is used to determine the classification of the samples based on the comparison of the signal output.

**4.2** The Evidence MultiSTAT System uses Randox Biochip Technology and performs simultaneous detection of multiple analytes from a single sample, using the Evidence MultiSTAT Analyzer. The assays are diagnostic tests for qualitative determination of the parent molecule and metabolites of drugs in human urine. The qualitative tests are based on a cut off value for each analyte, as detailed in the table below.

Table 3: Analytes, Associated Analyte in the Cut Off Material and Cut Off concentration employed in the Evidence MultiSTAT DOA Urine MultiPlex

| **Analyte** | **Analyte in Cut Off Material** | **Cut Off** |
|---|---|---|
| Methamphetamine | S-(+)-Methamphetamine | 500 ng/ml |
| Noroxycodone | Noroxycodone | 100 ng/ml |
| Benzodiazepines 1 | Oxazepam | 200 ng/ml |
| Methadone | (±)-Methadone | 300 ng/ml |

The Evidence MultiSTAT DOA Urine MultiPlex (EV4393) will be supplied as a test kit comprising:

- 12 x Urine Test Cartridges
- 6 x 1 ml Urine Cut Off Material (lyophilized)
- 4 x 1 ml Urine Positive Control Material (lyophilized)
- 2 x 10 ml Reconstitution Buffer
- 1 x USB which contains batch specific update and Instructions for Use (IFU)
- 1 x Batch Barcodes

Each kit is supplied with the Evidence MultiSTAT Accessory kit (EV4116) which contains:

- 12 x MultiSTAT Tip Cartridges
  - 1 x Tip/Waste Cartridge
  - 6 x 1000 µl Pipette Tip
  - 1 x Liquid Absorber

Reagent Composition

MultiSTAT DOA Urine MultiPlex Assay Diluent
20 mM phosphate buffer, pH 7.0 containing protein, detergents, and preservatives. This is contained within the cartridge.

MultiSTAT DOA Urine MultiPlex Conjugate
20 mM Tris based buffer, pH 7.0 containing protein, preservatives, and horseradish peroxidase - labelled drug derivatives. This is contained within the cartridge.

MultiSTAT DOA Urine MultiPlex Biochip
Solid substrate containing immobilized antibody discrete test regions. This is contained within the cartridge.

MultiSTAT DOA Urine MultiPlex Wash Buffer
20 mM Tris buffered saline, pH 7.4, containing surfactant and preservatives. This is contained within the cartridge.

LUM-EV934/PX
Luminol-EV934 and Peroxide are contained within the cartridge and are mixed in a ratio of 1:1 by the analyser to give the working signal reagent

MultiSTAT DOA Urine MultiPlex Cut Off
Lyophilised, 20 mM phosphate buffer, pH 7.2 containing stabilizers, preservatives and drug concentrations at the assay cut off values (detailed in Table 5 above).

MultiSTAT DOA Urine MultiPlex Positive Control
Lyophilised, 20 mM phosphate buffer, pH 7.2 containing stabilizers, preservatives, and drug concentrations.

MultiSTAT Reconstitution Buffer
A solution at a neutral pH containing preservatives.

## 5. Intended Use

The Evidence MultiSTAT DOA Urine MultiPlex is intended for use with the Evidence MultiSTAT. The Evidence MultiSTAT is an analyzer intended for the qualitative determination of parent drug molecule and metabolites of drugs in human urine at the associated cutoffs.

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For in vitro diagnostic use only.

## 6. Performance

Studies were performed to evaluate performance with regards to the precision, specificity, and accuracy of the candidate devices.

## 7. Conclusions

- Based on the information provided in this 510(k), the Evidence MultiSTAT Urine DOA MultiPlex, Evidence MultiSTAT, is substantially equivalent to the predicate devices and raise no new issues of safety and effectiveness.