01/23/2026

Randox Laboratories Limited
Karena Shaw
Regulatory Affairs Manager
55 Diamond Road
Crumlin, BT29 4QY
United Kingdom

Re: K250741
Trade/Device Name: Evidence MultiSTAT DOA Urine Multiplex
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG, DJC, DIS, DJR, DIO, LDJ, DKZ, JXM, LCM
Dated: January 15, 2026
Received: January 15, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2026.01.23 10:27:34 -05'00'

Joseph 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k250741

Device Name
Evidence MultiSTAT DOA Urine Multiplex

Indications for Use *(Describe)*
The Evidence MultiSTAT DOA Urine Mulitplex is intended for use with the Evidence MulitSTAT. The Evidence MultiSTAT is an analyser intended for the qualitative determination of parent drug molecule and metabolites of drugs in human urine at the associated cut offs.

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

Analyte	Analyte in Cut off Material	Cut Off
Methamphetamine	S-(+)-Methamphetamine	500ng/ml
Noroxycodone	Norocycodone	100ng/ml
Benzodiazepines 1	Oxazepam	200ng/ml
Methadone	(+)-Methadone	300ng/ml
Phenobarbital	Phenobarbital	200ng/ml
Tramadol	Tramadol	200ng/ml
Phencyclidine	Phencyclidine	25ng/ml
Buprenorphine	Norbuprenorphine	5ng/ml
6-Acetylmorphine	6-Acetylmorphine	10ng/ml
Fentanyl	Fentanyl	1ng/ml
Benzodiazepines 2	Lorazepam	200ng/ml
Opiates	Morphine	300ng/ml
Benzoylecgnonine/Cocaine	Benzoylecgnonine	150ng/ml
Cannabinoids (THC)	(-)-11-nor-9-Caboxy-Δ9-THC	50ng/ml
Amphetamine	S-(+)-Amphetamine	500ng/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) and 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K250741

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 (0) 28 9442 2413
Contact Person:	Karena Shaw
E-mail:	Karena.Shaw@randox.com

Date of Summary Preparation: 11th March 2025

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

510(k) Number:	k250741
Device Proprietary Names:	Evidence MultiSTAT DOA Urine MultiPlex
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 Toxicology (91). Regulatory information for the test system is detailed in table 1.

Table 1

Product Code	Classification Name	Classification	Regulation Section	Panel
DJC	Methamphetamine Test System	II	21 CFR 862.3610	Clinical Toxicology (91)
DJG	Opiate Test System	II	21 CFR 862.3650	Clinical Toxicology (91)
JXM	Benzodiazepine Test System	II	21 CFR 862.3170	Clinical Toxicology (91)
DJR	Methadone Test System (Methadone)	II	21 CFR 862.3620	Clinical Toxicology (91)
LCM	Phencyclidine Test System			Clinical Toxicology (91)
DIS	Barbiturate Test System (Phenobarbital)	II	21 CFR 862.3150	Clinical Toxicology (91)
DIO	Cocaine and cocaine metabolite test system (Benzoylecgonine/Cocaine)	II	21 CFR 862.3250	Clinical Toxicology (91)
LDJ	Cannabinoid test system (Cannabinoids (THC))	II	21 CFR 862.3870	Clinical Toxicology (91)
DKZ	Amphetamine test system (Amphetamine)	II	21 CFR 862.3100	Clinical Toxicology (91)

4. Predicate Devices Proprietary Names and 510(k) Numbers

The predicate device for the Evidence MultiSTAT DOA Urine MultiPlex is the Evidence MultiSTAT DOA Urine MultiPlex (k220451).

Table 2: Similarities and Differences to Predicate Device

Characteristic 510(k) number	Candidate Device (k250741)	Predicate Device (k220451)
Trade Name	Evidence MultiSTAT Urine DOA MultiPlex	Same
Model No.	EV4393	Same
510 (k) submitter/holder	Randox Laboratories Limited	Same
Indications for Use	Qualitative detection of drugs of abuse in urine	Same
Matrix	Urine	Same
Diagnostic Indication	Screening Method	Same
Population	Drug Use / Misuse	Same
Clinical Context	Laboratory	Same
Intended Use settings	IVD Prescription Use Only	Same
Methodology	Qualitative Immunoassay	Same
Analytes and Cutoff (ng/mL)	Fentanyl (1) Benzodiazepines 2 (200) Opiates (300) Benzoylecgonine/Cocaine (150) Cannabinoids (THC) (50) Amphetamine (500)	Benzodiazepines 1 (200) Methamphetamine (500) Noroxycodone (100) Methadone (300)

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 immobilized 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 DOA Urine MultiPlex 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
Phenobarbital	Phenobarbital	200 ng/ml
Tramadol	Tramadol	200 ng/ml
Phencyclidine	Phencyclidine	25 ng/ml
Buprenorphine	Norbuprenorphine	5 ng/ml
6-Acetylmorphine	6-Acetylmorphine	10 ng/ml
Fentanyl	Fentanyl	1 ng/ml
Benzodiazepines 2	Lorazepam	200 ng/ml
Opiates	Morphine	300 ng/ml
Benzoylecgonine/Cocaine	Benzoylecgonine	150 ng/ml
Cannabinoids (THC)	(-)-11-nor-9-Carboxy-Δ9-THC	50 ng/ml
Amphetamine	S-(+)-Amphetamine	500 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 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 3 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 analyser intended for the qualitative determination of parent drug molecule and metabolites of drugs in human urine at the associated cut offs.

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

Analyte	Analyte in Cut Off Material	Cut Off
Methamphetamine	S-(+)-Methamphetamine	500ng/ml
Noroxycodone	Noroxycodone	100ng/ml
Benzodiazepines 1	Oxazepam	200ng/ml
Methadone	(+)-Methadone	300ng/ml
Phenobarbital	Phenobarbital	200ng/ml
Tramadol	Tramadol	200ng/ml
Phencyclidine	Phencyclidine	25ng/ml
Buprenorphine	Norbuprenorphine	5ng/ml
6-Acetylmorphine	6-Acetylmorphine	10ng/ml
Fentanyl	Fentanyl	1ng/ml
Benzodiazepines 2	Lorazepam	200ng/ml
Opiates	Morphine	300ng/ml
Benzoylecgonine/Cocaine	Benzoylecgonine	150ng/ml
Cannabinoids (THC)	(-)-11-nor-9-Carboxy-Δ9-THC	50ng/ml
Amphetamine	S-(+)-Amphetamine	500ng/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.

FOR PRESCRIPTION USE ONLY

6. Performance

Studies were performed to evaluate performance with regards to precision & cut-off characterisation, analytical sensitivity/detection limit, analytical specificity/interference, method comparison.

7. Conclusions

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