Microgenics Corporation
Amrit Takhar
Regulatory Affairs Specialist III
46500 Kato Road
Fremont, California 94538

Re: K240670
Trade/Device Name: DRI™ Ecstasy Plus Assay
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ
Dated: October 4, 2024
Received: October 4, 2024

Dear Amrit Takhar:

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.

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: 2024.10.30 09:41:12 -04'00'

Joseph Kotarek, Ph.D.
Branch Chief for Toxicology
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)*
K240670

Device Name
DRI™ Ecstasy Plus Assay

Indications for Use *(Describe)*
The DRI™ Ecstasy Plus Assay is a homogeneous enzyme immunoassay intended for the qualitative or semiquantitative determination of ecstasy drugs in human urine. The assay provides a simple and rapid analytical screening procedure for detecting ecstasy drugs at a cutoff level of 500 ng/mL. The product is intended for use in clinical laboratories only.

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) or Liquid chromatography with tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

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.

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510K Summary
K240670

I. Device Information

Contact Details	
Sponsor:	Microgenics Corporation Thermo Fisher Scientific 46500 Kato Road Fremont, CA 94538 Phone: 510-979-5000 FAX: 510-979-5002
Correspondent Contact Information:	Amrit Takhar Regulatory Affairs Specialist III, Regulatory Affairs Email: Amrit.Takhar@thermofisher.com Phone: 510- 771-5935 FAX: 510-979-5002
Device Name	
Device Trade Name:	DRI™ Ecstasy Plus Assay
Common Name:	Amphetamine Test System
Classification Name:	Enzyme Immunoassay, Amphetamine
Regulation Number:	862.3100
Product Code:	DKZ
Legally Marketed Predicate Device	
Predicate Premarket Notification Number:	K012110
Predicate Trade Name:	DRI Ecstasy Enzyme Immunoassay
Predicate Common Name:	Amphetamine Test System
Predicate Classification Name:	Enzyme Immunoassay, Amphetamine
Predicate Regulation Number:	862.3100
Predicate Product Code:	DKZ

II. Date Summary Prepared

March 8, 2024

III. Description of Device

DRI Ecstasy Plus Assay is a homogeneous enzyme immunoassay intended for the qualitative or semiquantitative determination of ecstasy drugs in human urine. The assay provides a simple and rapid analytical screening procedure for detecting ecstasy drugs at a cutoff level of 500 ng/mL.

DRI Ecstasy Plus Assay is a class assay. Ecstasy drugs represent a group of ring substituted methylenedioxy analogues of amphetamine including 3, 4 – methylenedioxyamphetamine (MDA), 3, 4 – methylenedioxymethamphetamine (MDMA) and 3, 4 – methylenedioxyethylamphetamine (MDEA). They are central nervous system

(CNS) stimulants popularly abused for their psychotropic effects and are listed by the U.S. Drug Enforcement Administration as Schedule I (no accepted medical application with great abuse potential). At low dose, both MDMA and MDA produce euphoria, increased self-awareness, and an increased sense of trust. At higher doses, they are thought to be hallucinogenic. Toxic effects are similar to those of other CNS stimulants and include anxiety, depression, tachycardia, elevated blood pressure, cardiac arrhythmias, pupil dilation, and sleep disorders.

The length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life and the drug user's age, weight, activity and diet. Within the body, MDMA is known to metabolize to MDA by N-demethylation. Urinary excretion accounts for 65% of the dose as parent drug and 7% as MDA within 3 days. Urinary MDMA concentrations following a 1.5 mg/kg oral dose may exceed 17 mg/L. Other urinary metabolites include mono- and dihydroxy-derivatives of MDMA and MDA, resulting from fission of the methylene bridge, which are eliminated as conjugates. The human metabolism of MDA has not been studied. Urine concentrations in fatal cases of up to 160 mg/L have been recorded and are indicative of excretion of substantial portions of unchanged drugs.

Therefore, DRI Ecstasy Plus Assay is a first-line device, which may be used by medical personnel, along with clinical observations, as an aid to diagnosis of ecstasy abuse.

IV. Intended Use

A. Indications for Use:

See indications for use below.

B. Intended Use:

The DRI™ Ecstasy Plus Assay is a homogeneous enzyme immunoassay intended for the qualitative or semiquantitative determination of ecstasy drugs in human urine. The assay provides a simple and rapid analytical screening procedure for detecting ecstasy drugs at a cutoff level of 500 ng/mL. The product is intended for use in clinical laboratories only.

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) or Liquid chromatography with tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

V. Comparison to Predicate Device

Characteristics	**Predicate Device** DRI Ecstasy Enzyme Immunoassay (K012110)	**Candidate Device** DRI Ecstasy Plus Assay	Comparison
Indications for Use	See intended use below for indications use	See intended use below for indications use	Identical
Intended Use	The DRI Ecstasy Enzyme Immunoassay is a homogeneous enzyme immunoassay intended for the qualitative or semiquantitative determination of ecstasy drugs in human urine. The assay provides a simple and rapid analytical screening procedure for detecting ecstasy drugs at a Cutoff level of 500ng/mL. The product is intended for use in clinical laboratories only. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.	The DRITM Ecstasy Plus Assay is a homogeneous enzyme immunoassay intended for the qualitative or semiquantitative determination of ecstasy drugs in human urine. The assay provides a simple and rapid analytical screening procedure for detecting ecstasy drugs at a cutoff level of 500 ng/mL. The product is intended for use in clinical laboratories only. 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) or Liquid chromatography with tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.	Identical with expectation to additional confirmatory method option added. This does not impact the intended use of device.
FDA Product Code	DKZ	DKZ	Identical
Device Classification and Name	21 CFR 862.3100 Amphetamine Test System	21 CFR 862.3100 Amphetamine Test System	Identical
Operating Principle (Technology)	DRI	DRI	Identical
Analyte	Ecstasy	Ecstasy	Identical
Measured Analyte	3, 4 – methylenedioxyamphetamine (MDA) 3, 4 – methylenedioxymethamphetamine (MDMA)	3, 4 – methylenedioxyamphetamine (MDA) 3, 4 – methylenedioxymethamphetamine (MDMA)	Identical
Test Matrix	Human Urine	Human Urine	Identical

Characteristics	**Predicate Device** DRI Ecstasy Enzyme Immunoassay (K012110)	**Candidate Device** DRI Ecstasy Plus Assay	Comparison
Cut-off Levels	500 ng/mL	500 ng/mL	Identical
Methodology	Homogeneous Enzyme Immunoassay	Homogeneous Enzyme Immunoassay	Identical
Materials	Antibody/Substrate Reagent (R1) contains mouse monoclonal anti-MDMA antibody, glucose-6-phosphate (G6P), and nicotinamide adenine dinucleotide (NAD) in Tris buffer with sodium azide as a preservative. Enzyme Conjugate Reagent (R2) contains MDMA labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with sodium azide as a preservative.	Antibody/Substrate Reagent (R1) contains mouse monoclonal anti-MDMA antibody, glucose-6-phosphate (G6P), and nicotinamide adenine dinucleotide (NAD) in Tris buffer with sodium azide as a preservative. Enzyme Conjugate Reagent (R2) contains MDMA labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with sodium azide as a preservative.	Identical
Reagent Form	Reagents are sold in two sizes, 100 mL and 500 mL kits.	Reagents are sold in one size, 500 mL kit.	Identical
Antibody	Mouse Monoclonal Antibodies	Mouse Monoclonal Antibodies	Identical
Storage	2–8°C until expiration date	2–8°C until expiration date	Identical
Principal Operator	Trained professionals	Trained professionals	Identical
Instrument	Hitachi 717	Abbott Architect C4000	Different
Package Insert	Header and Footer Additional Material Precautious and Warning Specimen Collection and Preparation Reference	Header and Footer Additional Material Precautious and Warning Specimen Collection and Preparation Reference	Different
Product Labeling	Kit Labeling Component Labeling	Kit Labeling Component Labeling	Different
Performance Characteristics	Precision Accuracy Specificity (structurally related) Sensitivity	Precision Accuracy Specificity (structurally related)	Different

VI. Summary of Performance Testing

A. Precision:

In Qualitative, assay within run is ≤ 2% CV and total run precision is ≤ 5.0 % CV.
In Semi-Quantitative, assay within run is ≤ 5% CV and total run precision is ≤ 7.5 % CV

B. Method Comparison:

Negative sample agreement is 100% in both Qualitative and Semi-Quantitative modes.
Positive sample agreement is 100% in both Qualitative and Semi-Quantitative modes.
Overall sample agreement is 100%for DRI Ecstasy Plus assay in both Qualitative and Semi-Quantitative mode.

C. Specificity:

Structurally related compounds that produced a positive result above the cut-off calibrator were reported at lowest concentrations.
Structurally related compounds that produced a negative result below the cut-off calibrator were reported at the highest concentrations.
Structurally unrelated compounds shall produce a negative result below the 500 ng/mL MDMA sample in both Qualitative and Semi-quantitative modes at the concentrations tested.

In both Qualitative and Semi-quantitative modes, assay produced a negative result below the 500 ng/mL MDMA cutoff when structurally unrelated compounds were spiked into negative pool urine at the tested concentrations.

<u>Interference</u>
In Qualitative mode, the rates of the low control samples spiked with interfering substances and pH adjusted were negative, and the rates of the high control samples spiked with interference substances and pH adjusted were positive.

In Qualitative mode, the rates of the low control level samples were negative, and the rates of the high control level samples were positive.

In Semi-quantitative mode, the recovery of the low control level sample spiked with interfering substances and pH adjusted were within 80 - 120% of the nominal value of 375 ng/mL, and recovery of the high control level sample spiked with interfering substances and pH adjusted were within 80 - 120% of the nominal value of 625 ng/mL ng/mL.

D. Stability:

The results from the open-vial condition (in-use) demonstrated that three lots of DRI Ecstasy Plus Reagent Kit, 500 mL kit met the acceptance criteria. The results demonstrate that the product is stable over the shelf life once opened and stored tightly

capped at 2-8°C. These results support the claim that the DRI Ecstasy Plus Reagent Kit, 500mL kits are stable for 36 months when stored unopened at 2-8°C.

VII. Conclusion

The information supports a determination of substantial equivalence between the candidate device DRI Ecstasy Plus and the predicate device DRI Ecstasy Enzyme Immunoassay (K012110).