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

Re: K231007
Trade/Device Name: CEDIA™ Heroin Metabolite (6-AM) Assay
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG
Dated: August 11, 2023
Received: August 15, 2023

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 (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: 2023.09.27 17:25:56 -04'00'

Joseph Kotarek
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)*
K231007

Device Name
CEDIATM Heroin Metabolite (6-AM) Assay

Indications for Use *(Describe)*
The CEDIATM Heroin Metabolite (6-AM) Assay is a homogeneous enzyme immunoassay for the in vitro qualitative and/or semi-quantitative determination of the presence of heroin metabolite (6-AM) in human urine at a cut-off concentration of 10 ng/mL. The assay is intended to be used in laboratories and provides a rapid analytical screening procedure to detect 6-Acetylmorphine in human urine. The assay is designed for use with a number of clinical chemistry analyzers. This product is intended to be used by trained professionals only.

The semi-quantitative mode is for the purpose of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Liquid Chromatography/tandem mass spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

The assay 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) or Liquid chromatography with tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method.

Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used. 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.

510K Summary
K231007

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 II, Regulatory Affairs Email: Amrit.Takhar@thermofisher.com Phone: 510-979-5000 FAX: 510-979-5002
Device Name	
Device Trade Name:	CEDIA™ Heroin Metabolite (6-AM) Assay
Common Name:	Opiate Test System
Classification Name:	Enzyme Immunoassay, Opiates
Regulation Number:	862.3650
Product Code:	DJG
Legally Marketed Predicate Device	
Predicate Premarket Notification Number:	K192943
Predicate Trade Name:	CEDIA™ Heroin Metabolite (6-AM) Assay
Predicate Common Name:	Opiate Test System
Predicate Classification Name:	Enzyme Immunoassay, Opiates
Predicate Regulation Number:	862.3650
Predicate Product Code:	DJG

II. Date Summary Prepared

September 27, 2023

III. Description of Device

CEDIA technology uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system. The assay is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously re-associate to form fully active enzymes that, in the assay format, cleave a substrate. This generates a color change that can be measured spectrophotometrically.

CEDIA™ Heroin Metabolite (6-AM) Assay is supplied as a two liquid and two lyophilized reagent kit homogeneous enzyme immunoassay. The assay uses an antibody that is specific for 6-Acetylmorphine and cross reacts with Heroin. The assay has minimal cross-

reactivity to structurally related and unrelated compounds. In the assay, analyte in the sample competes with analyte conjugated to one inactive fragment of β-galactosidase for antibody binding site. If analyte is present in the sample, it binds to antibody, leaving the inactive enzyme fragments free to form active enzyme. If analyte is not present in the sample, antibody binds to analyte conjugated on the inactive fragment, inhibiting the re-association of inactive β- galactosidase fragments, and no active enzyme is formed. The amount of active enzyme formed and resultant absorbance change are directly proportional to the amount of drug present in the sample.

IV. Intended Use

A. Indications for Use:

See indications for use below.

B. Intended Use:

The CEDIA™ Heroin Metabolite (6-AM) Assay is a homogeneous enzyme immunoassay for the in vitro qualitative and/or semi-quantitative determination of the presence of heroin metabolite (6-AM) in human urine at a cut-off concentration of 10 ng/mL. The assay is intended to be used in laboratories and provides a rapid analytical screening procedure to detect 6-Acetylmorphine in human urine. The assay is designed for use with a number of clinical chemistry analyzers. This product is intended to be used by trained professionals only.

The semi-quantitative mode is for the purpose of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Liquid Chromatography/tandem mass spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

The assay 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) or Liquid chromatography with tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method.

Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used. For In Vitro Diagnostic Use Only.

V. Comparison to Predicate Device

Characteristics	**Candidate Device** CEDIA™ Heroin Metabolite (6-AM) Assay	**Predicate Device** CEDIA™ Heroin Metabolite (6-AM) Assay (K192943)	**Comparison**
Indications for Use	See intended use below for indications use	See intended use below for indications use	Identical

Characteristics	**Candidate Device** CEDIA™ Heroin Metabolite (6-AM) Assay	**Predicate Device** CEDIA™ Heroin Metabolite (6-AM) Assay (K192943)	Comparison
Intended Use	The CEDIA™ Heroin Metabolite (6-AM) Assay is a homogeneous enzyme immunoassay for the in vitro qualitative and/or semi-quantitative determination of the presence of heroin metabolite (6-AM) in human urine at a cut-off concentration of 10 ng/mL. The assay is intended to be used in laboratories and provides a rapid analytical screening procedure to detect 6-Acetylmorphine in human urine. The assay is designed for use with a number of clinical chemistry analyzers. This product is intended to be used by trained professionals only. The semi-quantitative mode is for the purpose of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Liquid Chromatography/tandem mass spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures. The assay provides only a preliminary analytical test result. A more specific alternative chemical	The CEDIA™ Heroin Metabolite (6-Acetylmorphine, or 6-AM) Assay is a homogeneous enzyme immunoassay for the in vitro qualitative and/or semi-quantitative determination of the presence of heroin metabolite (6-AM) in human urine at a cut-off concentration of 10 ng/mL. The assay is intended to be used in laboratories and provides a rapid analytical screening procedure to detect 6-Acetylmorphine in human urine. The assay is designed for use with a number of clinical chemistry analyzers. This product is intended to be used by trained professionals only. The semi-quantitative mode is for the purpose of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Liquid Chromatography/tandem mass spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures. The assay provides only a preliminary analytical test result. A more specific	Identical

Characteristics	**Candidate Device** CEDIA™ Heroin Metabolite (6-AM) Assay	**Predicate Device** CEDIA™ Heroin Metabolite (6-AM) Assay (K192943)	Comparison
	method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/ mass spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used. For In Vitro Diagnostic Use Only.	alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/ mass spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used. For In Vitro Diagnostic Use Only.	
FDA Product Code	DJG	DJG	Identical
Device Classification and Name	Class II, 21 CFR 862.3650 – Opiate test system, 91 – Toxicology	Class II, 21 CFR 862.3650 – Opiate test system, 91 – Toxicology	Identical
Operating Principle (Technology)	CEDIA	CEDIA	Identical
Analyte	6-Acetylmorphine	6-Acetylmorphine	Identical

Characteristics	**Candidate Device** CEDIA™ Heroin Metabolite (6-AM) Assay	**Predicate Device** CEDIA™ Heroin Metabolite (6-AM) Assay (K192943)	Comparison
Measured Analyte	Heroin and 6-Acetylmorphine	Heroin and 6-Acetylmorphine	Identical
Test Matrix	Human Urine	Human Urine	Identical
Cut-off Levels	10 ng/mL	10 ng/mL	Identical
Methodology	Homogeneous Enzyme Immunoassay	Homogeneous Enzyme Immunoassay	Identical
Materials	Assay contains buffer salts, stabilizer, and preservative, BSA. Assay contains mouse monoclonal anti-6-Acetylmorphine derivative antibody, Enzyme Acceptor (Escherichia Coli), and Enzyme Donor (Escherichia Coli) Conjugated to 6-Acetylmorphine derivative	Assay contains buffer salts, stabilizer, and preservative, BSA. Assay contains mouse monoclonal anti-6-Acetylmorphine derivative antibody, Enzyme Acceptor (Escherichia Coli), and Enzyme Donor (Escherichia Coli) Conjugated to 6-Acetylmorphine derivative	Identical
Reagent Form	EA and ED: Lyophilized (Reconstitution Required) EARB and EDRB: Liquid ready-to-use	EA and ED: Lyophilized (Reconstitution Required) EARB and EDRB: Liquid ready-to-use	Identical

Characteristics	**Candidate Device** CEDIA™ Heroin Metabolite (6-AM) Assay	**Predicate Device** CEDIA™ Heroin Metabolite (6-AM) Assay (K192943)	Comparison
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	Horiba Yumizen C1200	Horiba Pentra C400	Different clinical chemistry Analyzer

VI. Summary of Performance Testing

A. Precision:

For Qualitative and semi-quantitative mode, ≥ 95% of samples below the cutoff read as negative and ≥ 95% of samples above the cutoff read as positive.

B. Spike Recovery:

In qualitative mode, there is no ± 2SD overlap between the spiked 10 ng/mL, 7.5 and 12.5 ng/mL samples. All 20 replicates of spiked 7.5 ng/mL and 12.5 ng/mL samples are detected as Negative and Positive, respectively, when compared to 10 ng/mL spiked sample.

In semi-quantitative mode, the spiked samples recover within 80–120% of the nominal values.

C. Dilution Linearity:

The assay demonstrates linearity throughout the calibration range of 0 to 20 ng/mL and R > 0.99. The mean recovery at each level is within 80–120% of expected values.

D. Method Comparison:

The negative agreement in qualitative mode is 100% and semi-quantitative mode is 98.4%. The positive agreement in qualitative mode is 100% and Semi-quantitative mode is 98.3%. The overall correlation agreement in Qualitative mode is 100% and Semi-quantitative mode is 98.4%.

E. Specificity:

Cross-Reactivity

The assay is specific for 6-Acetylmorphine and demonstrates cross-reactivity to heroin. Minimal cross-reactivity is observed with other structurally related and unrelated compounds.

Interference

Results demonstrate that there is no significant interference from the endogenous and exogenous substances in human urine at the tested concentrations, in samples within pH range of 3–11 and in samples with specific gravity within 1.000–1.030.

F. Stability:

Reagent On-Board Stability

Reagent On-Board stability studies for one lot stored on-board clinical analyzer supports the claim of 60 days for qualitative and semi-quantitative modes.

Reconstituted Reagent Stability

Reconstituted Reagent stability studies for one lot stored at 2–8°C supports the claim of 60 days for qualitative and semi-quantitative modes.

Open Vial Stability

Open Vial stability studies for one lot stored at 2–8°C supports the claim of 60 days for qualitative and semi-quantitative modes. This data was presented in the original 510(k) submission K192943.

Real Time Stability for Reagent

Real time stability studies for three lots of reagents stored at 2–8°C have been carried out for up to 26 months. Proposed shelf-life claim is 24 months. This data was presented in the 510(k) submission K192943.

VII. Conclusion

The information supports a determination of substantial equivalence between CEDIA™ Heroin Metabolite (6-AM) Assay and the predicate device CEDIA™ Heroin Metabolite (6-AM) Assay (K192943).