November 22, 2017

Microgenics Corporation
Minoti Patel
Manager, Regulatory Affairs
46500 Kato Road
Fremont, California 94538

Re: K173183
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: September 28, 2017
Received: October 2, 2017

Dear Minoti Patel:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stayce Beck -A

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173183

Device Name
CEDIA Heroin Metabolite (6-AM) Assay

Indications for Use *(Describe)*

CEDIA Heroin Metabolite (6-AM) Assay:

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 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.

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.

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k173183

510(k) Summary

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of Safe Medical Device Act of 1990 and 21 CFR 807.92.

A. Device Information

Category	Comments
Sponsor:	Microgenics Corporation Thermo Fisher Scientific 46500 Kato Road Fremont, CA 94538 Phone: 510-979-5000 FAX: 510-979-5002
Correspondent Contact Information:	Minoti Patel, RAC Manager, Regulatory Affairs Email: Minoti.patel@thermofisher.com Phone: 510-979-5000 FAX: 510-979-5002
Device Common Name:	6-Acetylmorphine Immunoassay Test System
Trade or Proprietary Name	CEDIA Heroin Metabolite (6-AM) Assay
Candidate Device Product Code, Classification, Classification,Name & Panel	DJG, Class II, 21 CFR 862.3650 – Opiate test system, 91 – Toxicology

Predicate Device Information:

Predicate Device:	CEDIA DAU 6-AcetylmorphineAssay
Predicate Device Manufacturer:	Microgenics Corporation
Predicate Device Premarket Notification #:	k001178

B. Date Summary Prepared

November 21, 2017

C. Description of Device

The assay consists of buffers (1 and 2) and lyophilized reagents (1a and 2a). The components include mouse monoclonal antibodies to 6-Acetylmorphine, recombinant microbial enzyme donor (ED) – 6-Acetylmorphine conjugate; enzyme acceptor (EA), chlorophenol red β-D-galactopyranoside; stabilizers and preservatives. Calibrators and controls are sold separately.

D. Intended Use

CEDIA Heroin Metabolite (6-AM) Assay
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 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.

E. Comparison to Predicate Device

Characteristic	**Predicate Device:** CEDIA DAU 6-Acetylmorphine Assay (k001178)	**Candidate Device:** CEDIA Heroin Metabolite (6-AM) Assay
Intended Use	A homogeneous enzyme immunoassay for the in vitro qualitative or semi-quantitative determination of 6-Acetylmorphine in human urine at a cut-off concentration of 10 ng/mL	Same
Operating	CEDIA	Same

Characteristic	Predicate Device: CEDIA DAU 6-Acetylmorphine Assay (k001178)	Candidate Device: CEDIA Heroin Metabolite (6-AM) Assay
Principle (Technology)		
Measured Analyte	Heroin and 6-Acetylmorphine	Same
Test Matrix	Urine	Same
Cutoff Levels	10 ng/mL	Same
Methodology	Homogeneous Enzyme Immunoassay	Same
Reagents Form	EA and ED: liquid ready-to-use.	EA and ED: Lyophilized (Reconstitution Required) EARB and EDRB liquid ready-to-use.
Antibody	Mouse Monoclonal antibody	Same
Storage	2–8°C until expiration date.	Same
Principal Operator	Trained professionals	Same

F. Test Principle

The CEDIA Heroin Metabolite Assay uses recombinant DNA technology to produce a homogeneous enzyme immunoassay system. This assay is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments, termed Enzyme Acceptor (EA) and Enzyme Donor (ED) spontaneously re-associate to form a fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.

G. Summary of Supporting Data

1. Analytical Performance:

Performance was evaluated at the manufacturer's site on Beckman Coulter AU 680 Analyzer.

a) Precision

Precision studies were performed in accordance with CLSI Guideline EP05-A3. The study was performed for two runs per day, twice a day, for 20 days (total n=80). Samples were prepared by spiking 6-Acetylmorphine methanol stock solution into drug free urine at the cutoff, 25%, 50%, 75% & 100% above and below the cutoff and tested in both qualitative and semi-quantitative modes. The results are summarized in the tables below.

Qualitative Results:

% of Cutoff	Spiked Conc. (ng/mL)	GC/MS (ng/mL)	Within Run (n=80)	
			Number of determinants	Immunoassay Results
-100%	0	N/A	80	80 Negative
-75%	2.5	2.67	80	80 Negative
-50%	5	5.17	80	80 Negative
-25%	7.5	7.82	80	80 Negative
100%	10	10.2	80	56 Negative/ 24 Positive
+25%	12.5	12.8	80	80 Positive
+50%	15	15.2	80	80 Positive
+75%	17.5	18.0	80	80 Positive
+100%	20	21.5	80	80 Positive

Semi-Quantitative Results:

% of Cutoff	Spiked Conc. (ng/mL)	GC/MS (ng/mL)	Within Run (n=80)	
			Number of determinants	Immunoassay Results
-100%	0	N/A	80	80 Negative
-75%	2.5	2.67	80	80 Negative
-50%	5	5.17	80	80 Negative
-25%	7.5	7.82	80	80 Negative
100%	10	10.2	80	42 Negative/ 38 Positive
+25%	12.5	12.8	80	80 Positive
+50%	15	15.2	80	80 Positive
+75%	17.5	18.0	80	80 Positive
+100%	20	21.5	80	80 Positive

b) Spike Recovery

The study was performed for 20 replicates using reagents, calibrators and controls. This study was carried out by testing spiked samples containing 6-Acetylmorphine at the cutoff calibrator and controls levels. The spiked samples were prepared by spiking 6-Acetylmorphine into drug free negative urine. Samples were tested in both Qualitative and Semi-Quantitative mode. The qualitative and semi-quantitative results are summarized in the table below.

Replicate	7.5 ng/mL (n=20)	10 ng/mL (n=20) (Rate mA/min)	12.5 ng/mL (n=20)
1	Negative	515	Positive
2	Negative	513	Positive
3	Negative	515	Positive
4	Negative	515	Positive
5	Negative	516	Positive
6	Negative	513	Positive
7	Negative	512	Positive
8	Negative	519	Positive
9	Negative	515	Positive
10	Negative	517	Positive
11	Negative	517	Positive
12	Negative	518	Positive
13	Negative	518	Positive
14	Negative	517	Positive
15	Negative	515	Positive
16	Negative	516	Positive
17	Negative	520	Positive
18	Negative	515	Positive
19	Negative	516	Positive
20	Negative	518	Positive
Overlap	No	No	No
Relative to C/O	All 20 below C/O	N/A	All 20 above C/O

c) Analytical Recovery and Linearity

Linearity studies were performed in accordance with CLSI Guideline EP06-A. To demonstrate the linearity of the entire assay range, drug free urine was spiked to the high calibrator level (20ng/mL) by using 6-AM methanol solution and diluted with drug free urine to generate 10 intermediate levels.

Each sample was run in replicates of five in semi-quantitative mode and the average was used to determine percent recovery compared to the expected target value. The percent recovery is summarized in the table below.

Level	**Target Concentration (ng/mL)**	**Observed Concentration (ng/mL)**	**Recovery (%)**
1	0	0.18	N/A
2	2	2.26	113.0
3	4	4.02	100.5
4	6	6.10	101.7
5	8	7.86	98.3
6	10	9.88	98.8
7	12	11.90	99.2
8	14	13.72	98.0

9	16	15.52	97.0
10	18	18.04	100.2
11	20	19.64	98.2

d) Method Comparison and Accuracy

The method comparison study was performed in accordance with CLSI Guideline EP09-A3. One hundred unaltered patient samples were analyzed by the CEDIA Heroin Metabolite (6-Acetylmorphine) Assay in both qualitative and semi-quantitative modes and the results are compared to LC-MS/MS. The overall concordance between LC-MS/MS and CEDIA Heroin Metabolite (6-Acetylmorphine) Assay is 99%. The qualitative and semi-quantitative results are summarized in the tables below.

Qualitative Results

Candidate Device Results	Negative	< 50% of Cutoff concentration by LC-MS/MS (< 5ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration as determined by LC-MS/MS) (5 – 9.9 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration as determined by LC-MS/MS) (10 – 15.0 ng/mL)	High Positives (Greater than 50% above cutoff concentration (> 15.0 ng/mL)
Positive	0	0	1*	5	45
Negative	43	2	4	0	0

* Discordant sample

Agreement among Positives: 50/50 =100%
Agreement among Negative: 49/50=98%

Semi-Quantitative Results

Candidate Device Results	Negative	< 50% of Cutoff concentration by LC-MS/MS (< 5ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration as determined by LC-MS/MS) (5 – 9.9 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration as determined by LC-MS/MS) (10 – 15.0 ng/mL)	High Positives (Greater than 50% above cutoff concentration (> 15.0 ng/mL)
Positive	0	0	1*	5	45
Negative	43	2	4	0	0

* Discordant sample

Agreement among Positives: 50/50 =100%
Agreement among Negative: 49/50=98%

*** Discordant Result Summary**

	CEDIA 6-AM Urine Assay		LC-MS/MS (ng/mL)
Sample ID	Qualitative mode	Semi-Quantitative mode	6-Acetylmorphine
CA170418-025	Positive	Positive	9.61

Sample showed 13.8 ng/mL in semi-quantitative mode, and is discordant due to cross reactivity to morphine present in the sample at a concentration of 4449 ng/mL as measured by LC-MS/MS

e) Specificity

The cross-reactivity of Heroin Metabolite (6-AM) and its metabolites is evaluated by adding known amounts of each analyte to drug-free negative urine. As indicated by the results in the table below, 6-Acetylmorphine showed 100% cross-reactivity. Heroin showed 6% cross-reactivity.

Heroin Metabolite (6-AM) and its metabolites	Tested Concentration (ng/mL)	Cross-reactivity (%)
6-Acetylmorphine	10	100
Heroin	160	6

Cross Reactivity of Structurally Related or Unrelated Opiate Compounds

Opiates and Structurally Related Compounds	Tested Concentration (ng/mL)	Cross-reactivity (%)
6-Acetylcodeine	100,000	0.01
Buprenorphine	100,000	<0.01
Buprenorphine-3β-D-glucuronide	100,000	<0.01
Codeine	100,000	<0.01
Dextromethorphan	100,000	<0.01
Dihydrocodeine	100,000	<0.01
EDDP	100,000	<0.01
EMDP	100,000	<0.01
Ethylmorphine	100,000	<0.01
Fentanyl	100,000	<0.01
Hydrocodone	100,000	<0.01
Hydromorphone	20,000	0.05
Hydromorphone-3β-D-glucuronide	100,000	<0.01
LAAM	100,000	<0.01
Levorphanol	20,000	0.05
Methadone	100,000	<0.01
Meperidine	100,000	<0.01
Mitragynine	100,000	<0.01
7-Hydroxymitragynine	100,000	<0.01
Morphine	13,500	0.07
Morphine-3β-D-Glucuronide	100,000	<0.01
Morphine-6β-D-Glucuronide	100,000	<0.01

Nalorphine	10,500	0.10
Naloxone	100,000	<0.01
Naltrexone	100,000	<0.01
Norbuprenorphine	100,000	<0.01
Norbuprenorphine glucuronide	100,000	<0.01

Opiates and Structurally Related Compounds	Tested Concentration (ng/mL)	Cross-reactivity (%)
Norcodeine	100,000	<0.01
Norhydrocodone	100,000	<0.01
Normorphine	50,000	0.02
Norpropoxyphene	100,000	<0.01
Noroxycodone	100,000	<0.01
Noroxymorphone	100,000	<0.01
Oxycodone	100,000	<0.01
Oxymorphone	100,000	<0.01
Oxymorphone-3β-D-glucuronide	100,000	<0.01
Tapentadol HCl	100,000	<0.01
Tramadol	100,000	<0.01

The potential cross-reactivity posed by drugs commonly co-administered with Heroin Metabolite (6-AM) was evaluated by adding each substance to Heroin Metabolite (6-AM) spiked at Low Control, 7.5 ng/mL (-25% of the cutoff concentration) and the High Control, 12.5 ng/mL (+25% of the cutoff concentration) levels at the concentrations indicated. A drug is considered to cross-react if the observed Heroin Metabolite (6-AM) concentrations result exceed 10 ng/mL. As shown in the table below, all the pharmacologic compounds evaluated exhibited negligible cross reactivity at the concentrations tested.

Structurally Unrelated Compounds Spiked at the Concentration Listed Below into Low Control and High Control

Structurally Unrelated Compounds	Tested Conc. (ng/mL)	Spiked 6-Acetylmorphine level	
		Low Control	High Control
		Positive/ Negative	Positive/ Negative
10,11 Dihydrocarbamazepine	85,000	Negative	Positive
11-nor-delta9-THC-COOH	10,000	Negative	Positive
Acetaminophen	500,000	Negative	Positive
Acetylsalicylic Acid	500,000	Negative	Positive
Amitriptyline	125,000	Negative	Positive
Amoxicillin	500,000	Negative	Positive
Amphetamine	100,000	Negative	Positive
Amisulpride	100,000	Negative	Positive
Benzotropine Mesylate	125,000	Negative	Positive
Benzoylecgonine	100,000	Negative	Positive
Brompheniramine	75,000	Negative	Positive
Caffeine	500,000	Negative	Positive
Captopril	500,000	Negative	Positive
Chlordiazepoxide	100,000	Negative	Positive

Structurally Unrelated Compounds	Tested Conc. (ng/mL)	Spiked 6-Acetylmorphine level	
		Low Control	High Control
		Positive/ Negative	Positive/ Negative
Chlorpromazine	10,000	Negative	Positive
Clomipramine	250,000	Negative	Positive
Chloroquine	500,000	Negative	Positive
Cimetidine	500,000	Negative	Positive
Desipramine	125,000	Negative	Positive
Diazepam	100,000	Negative	Positive
Digoxin	100,000	Negative	Positive
Diphenhydramine	50,000	Negative	Positive
Doxepine HCl	50,000	Negative	Positive
Enalapril	500,000	Negative	Positive
Fluoxetine	500,000	Negative	Positive
Fluophenazine	500,000	Negative	Positive
Haloperidol	50,000	Negative	Positive
Hydroxychlroquine	100,000	Negative	Positive
Hydroxyzine	250,000	Negative	Positive
Ibuprofen	500,000	Negative	Positive
Imipramine	50,000	Negative	Positive
Levothyroxine	50,000	Negative	Positive
Methamphentamine	100,000	Negative	Positive
Maprotiline	500,000	Negative	Positive
Nalbuphine	100,000	Negative	Positive
Naproxen	500,000	Negative	Positive
Nortryptiline	250,000	Negative	Positive
Nifedipine	500,000	Negative	Positive
Nordiazepam	100,000	Negative	Positive
Oxazepam	100,000	Negative	Positive
Perphenazine	150,000	Negative	Positive
Phencyclidine	7,500	Negative	Positive
Phenobarbital	100,000	Negative	Positive
Procyclidine	400,000	Negative	Positive
Propoxyphene	25,000	Negative	Positive
Protriptyline	50,000	Negative	Positive
Ranitidine	500,000	Negative	Positive
Salicyluric Acid	500,000	Negative	Positive
Secobarbital	100,000	Negative	Positive
Sulpiride	500,000	Negative	Positive
Thioridazine	250,000	Negative	Positive
Triprolidine	125,000	Negative	Positive
Verapamil	500,000	Negative	Positive

f) Interference

The interference studies were performed in accordance with CLSI Guideline EP07-A2. The potential interference of pH and endogenous physiologic substances on recovery of 6-AM using CEDIA Heroin Metabolite (6-AM) Urine Assay was assessed by spiking known compounds of potentially interfering substances into the Low Control,7.5 ng/mL (-25% of the cutoff concentration) and the High Control, 12.5 ng/mL (+25% of the cutoff concentration). In the presence of the compounds listed below, the controls were detected accurately, indicating that these compounds did not show interference in the assay.

Compound	Tested Concentration (mg/dL)	Spiked 6-Acetylmorphine level	
		Low Control -25% of cutoff (7.5 ng/mL)	High Control +25% cutoff (12.5 ng/mL)
Acetone	1000	Negative	Positive
Ascorbic acid	1500	Negative	Positive
Creatinine	500	Negative	Positive
Ethanol	1000	Negative	Positive
Galactose	10	Negative	Positive
ϒ-globulin	500	Negative	Positive
Glucose	1000	Negative	Positive
Hemoglobin	300	Negative	Positive
Human serum albumin	500	Negative	Positive
Oxalic acid	100	Negative	Positive
Riboflavin	7.5	Negative	Positive
Sodium Chloride	6000	Negative	Positive
Urea	2000	Negative	Positive
pH			
pH	3	Negative	Positive
pH	4	Negative	Positive
pH	5	Negative	Positive
pH	6	Negative	Positive
pH	7	Negative	Positive
pH	8	Negative	Positive
pH	9	Negative	Positive
pH	10	Negative	Positive
pH	11*	Negative	Negative

***** pH 11 urine interferes CEDIA 6-AM urine assay.

Specific Gravity

Drug free urine samples with specific gravity ranging in value within 1.002 to 1.030 were split and spiked to a final concentration of either 7.5 ng/mL or 12.5 ng/mL (the

Low Control and High Control concentrations, respectively). These samples were then evaluated in both qualitative and semi-quantitative modes. No interference was observed.

Specific Gravity	Spiked 6-Acetylmorphine Concentration	
	Low Control	High Control
1.004	Negative	Positive
1.005	Negative	Positive
1.007	Negative	Positive
1.010	Negative	Positive
1.011	Negative	Positive
1.013	Negative	Positive
1.019	Negative	Positive
1.023	Negative	Positive
1.025	Negative	Positive
1.029	Negative	Positive

g) Clinical cutoff

SAMHSA guideline for 6-Acetylmorphine is 10 ng/mL cutoff.

H. Conclusion

The information supports a determination of substantial equivalence between CEDIA Heroin Metabolite (6-AM) Assay and the predicate device CEDIA DAU 6-Acetylmorphine Assay (k001178).