June 25, 2021

Psychemedics Corporation
Neil Stowe
Principal Scientist
5832 Uplander Way
Culver City, California 90230

Re: K201228
Trade/Device Name: Psychemedics Homogeneous Enzyme Immunoassay for Cocaine in Hair
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and Cocaine Metabolite Test System
Regulatory Class: Class II
Product Code: JXO
Dated: October 26, 2020
Received: October 27, 2020

Dear Neil Stowe:

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,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201228

Device Name
Psychemedics Homogeneous Enzyme Immunoassay for Cocaine in Hair

Indications for Use *(Describe)*
The Psychemedics homogeneous enzyme immunoassay for cocaine in hair is an enzyme immunoassay for the preliminary qualitative detection of cocaine in human head and body hair using a cocaine calibrator of 5 ng/10 mg hair for the purpose of identifying cocaine use. This product is intended exclusively for in-house professional use and not for sale to anyone.

The Psychemedics EIA Cocaine Assay provides only a preliminary analytical test result. To confirm positive results, a more specific alternate chemical method (e.g. LC/MS/MS) must be used. Clinical consideration and professional judgement should be applied to the interpretation of any drug-of-abuse test result.

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."

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k201228

Submitted By: Psychemedics Corporation

5832 Uplander Way

Culver City, CA 90230

TEL: 310 216 7776

FAX: 310 216 6662

Submission Contact: Neil Stowe

Date Prepared: 10-26-2020

Device Trade Name: Psychemedics Homogeneous Enzyme Immunoassay for Cocaine in Hair

Predicate Device: Psychemedics Microplate EIA for Cocaine in Hair, k111925

Product Code: JXO

Device/Classification Name: 21 CFR 862.3250 Cocaine and Cocaine Metabolite Test System, Classification II

Intended Use: The Psychemedics homogeneous enzyme immunoassay for cocaine in hair is an enzyme immunoassay for the preliminary qualitative detection of cocaine in human head and body hair using a cocaine calibrator of 5 ng/10 mg hair for the purpose of identifying cocaine use. This product is intended exclusively for in-house professional use and is not for sale to anyone.

The Psychemedics HEIA Cocaine Assay provides only a preliminary analytical test result. To confirm positive results, a more specific alternate chemical method (e.g. LC/MS/MS) must be used. Clinical consideration and professional judgement should be applied to the interpretation of any drug-of-abuse test result.

Device Description: The homogeneous enzyme immunoassay (HEIA) test consists of two parts; a pre-analytical hair treatment procedure (to extract cocaine from the solid hair matrix to a measurable liquid matrix) and the screening assay, the Psychemedics Cocaine HEIA. The screening portion of the test system is based on competition for antibody binding sites between drug in the measurable liquid matrix and drug-labeled recombinant glucose-6-phosphate dehydrogenase (G6PDH). As the antibody binds labeled G6PDH, enzyme activity decreases. In the presence of drug, enzyme activity increases in direct proportion to the drug concentration. Active enzyme reduces nicotinamide adenine dinucleotide (NAD) to NADH in the presence of glucose-6-phosphate (G6P), resulting in an absorbance change that is measured spectrophotometrically.

	The Psychemedics Cocaine HEIA consists of reagents R1 (anti-cocaine monoclonal antibody with substrate) and R2 (cocaine labeled recombinant G6PDH).
Sample Collection and Stability:	A sample of hair should be cut as close as possible to the skin. The hair is placed in a V-shaped aluminum foil sample holder with the root end of the hair protruding beyond the slanted edge of the foil. The aluminum foil is crimped around the sample, securing the hair specimen firmly into place within the foil. The hair sample, crimped within the foil, is placed in a sample acquisition card envelope and the envelope is sealed with a tamper-evident seal. Hair specimens are kept at ambient temperature in a secure location until they are shipped without refrigeration to the laboratory. Stability of cocaine in hair samples stored at room temperature has been shown for approximately 6 months. Cocaine in samples shipped coast-to-coast twice was stable.
Materials Required:	Hair sample collection kit, HEIA for Cocaine, automated clinical chemistry analyzer, LC/MS/MS for confirmation.

Comparison with Predicate:

Item	Proposed Device	Psychemedics Cocaine Assay, k111925
Indications/Intended Use	The Psychemedics homogeneous enzyme immunoassay for cocaine in hair is an enzyme immunoassay for the preliminary qualitative detection of cocaine in human head and body hair using a cocaine calibrator of 5 ng/10 mg hair for the purpose of identifying cocaine use. This product is intended exclusively for in-house professional use and not for sale to anyone. The Psychemedics EIA Cocaine Assay provides only a preliminary analytical test result. To confirm positive results, a more specific alternate chemical method (e.g. LC/MS/MS) must be used. Clinical consideration and professional judgement should be applied to the interpretation of any drug-of-abuse test result.	The Psychemedics Microplate EIA for Cocaine is an enzyme immunoassay (EIA) for the preliminary qualitative detection of cocaine in human head and body hair samples using a cocaine calibrator at 5 ng/10 mg hair cutoff for the purpose of identifying cocaine use. This product is intended exclusively for in-house professional use and not for sale to anyone. The test is not intended for over-the-counter sale to non-professionals. The Psychemedics EIA Cocaine Assay provides only a preliminary analytical test result. To confirm positive results, a more specific alternate chemical method (e.g. LC/MS/MS) must be used. Clinical consideration and professional judgement should be applied to the interpretation of any drug-of-abuse test result.
Product Code	JXO	JXO
Measurand	Cocaine	Cocaine
Test System	Psychemedics Homogeneous Enzyme Immunoassay for Cocaine in Hair	Psychemedics Microplate EIA for Cocaine in Hair
Sample Matrix	Human Hair	Human Hair
Method of Measurement	Automated Clinical Chemistry Analyzer at 340 nm	Microplate Reader at 450 nm
Type of Test	Enzyme Immunoassay	Enzyme Immunoassay
Extraction Method	Acidic aqueous buffer	Patented Digestion Method
Confirmation Method	LC/MS/MS	LC/MS/MS

Performance Testing Summary: Precision studies were performed by spiking negative hair with previously LC/MS/MS validated calibrator and control solutions to achieve concentrations of negative, the cutoff calibrator of 5 ng cocaine/10 mg hair, and +/- 75%, +/- 50% and +/-25% of the cutoff calibrator.

Summary Intra-Assay Precision				Summary Inter-Assay Precision		
Level	NEG	POS		Level	NEG	POS
-100%	8	0		-100%	80	0
-75%	8	0		-75%	80	0
-50%	8	0		-50%	80	0
-25%	8	0		-25%	80	0
+25%	0	8		+25%	0	80
+50	0	8		+50	0	80
+75%	0	8		+75%	0	80
+100%	0	8		+100%	0	80

Cross Reactivity Summary: The cross reactivity of the following metabolites and cocaine structural analogs was evaluated by determining the minimum concentration that would result approximately equivalent to the 5.0 ng cocaine/10 mg hair cutoff.

Cross Reactivities of Structurally Related Compounds and Metabolites		
Compound	% Cross Reactivity	Concentration Equivalent to 5.0 ng Cocaine/10 mg Hair
Benzoylecgonine	2.0	250
Norcocaine	20	25
Cocaethylene	55.5	9
Ecgonine	< 1	>500
Ecgonine Methyl Ester	<1	>500
Anhydroecgonine Methyl Ester	<1	>500

The following compounds were shown to have no cross reactivity in the Cocaine assay.

Lisinopril Dihydrate, Atropine, Bupropion, Cotinine, Cannabinol, Chlorpheniramine Maleate, O-Desmethylvenlafaxine, Desipiramine, Doxylamine Succinate, 1S, 2R-Ephedrine, Amitriptyline, Dextromethorphan, Lidocaine, Methocarbamol, Nordoxepin, Pentazocine, Phenylephrine, Triamterene, Naproxen, Nicotine, Nortriptyline, Propoxyphene, R,R-Pseudoepedrine, Thioridazine, Cis-Tramadol, Venlafaxine HCl, 8-(-)11-nor-9-carboxy-delta 9 THC, 11-nor-9-carboxy-delta 9 THC, Amoxicillin, Propanolol, Promethazine, Phenmetrazine, Phendimetrazine, Benzocaine, Dimenhydrinate, Metanephrin, Carbamazepine, Diazepine, Nordiazepam, Oxazepam, Acetominophen, Caffeine, Dyphylline, Methaqualone, Theophylline, Amphetamine, Cetrizine DiHCl, Imipramine, Methamphetamine, Phencyclidine, Phenylpropanolamine, Amitryptiline, Bupivacaine HCl, Lidocaine, Methocarbamol, Nordoxepin, Pentazocine, Pheynylephrine, Triamterene, Ethosuximide, Alpha-methyl-alpha-propyl succinimide, Metharbital, Barbital, Mehsuximde, Phensuximide, N-Normethsuximide, Mephyton, Ethotoin, Mephobarbital, PEMA, Phenobarbital, Methyl PEMA, 10, 11-Dihydrocarbamazepine, Primidone, 5,5-Diphenylhydantoin, 4-Methylprimidone, Butabarbital, Amobarbital, Secobarbital, Hexobarbital, Azithromyocin Dihydrate, Glutethimide, Methaqualone, Diazepam, Chlorpromazine, Flurazepam, AM-2201, JWH-019, JWH-081, JWH-122, CP47,497 (+/-), CP47, 497 (+/-), C8 Homologue, HU-211, JWH-200, JWH-250, Ibuprofen,

Ephinephrine (+/-), Norephenephrine (+/-), Metanephrine (+/-), Normetanephrine (+/-), Vanilmandelic Acid (+/-), 5-Hydroxyindole-3-acetic acid, Homovanillic acid, Alprazolam, Cimetidine, Citalopram HBr, Clonazepam, Clopidogrel bisulfate, Fluconazole, hydrochlorothiazide, Lamotrigeine, L-Thyroxine, Methylphenidate HCl, Omeprazole, Levetiracetam, Sertaline HCl, Topiramate, Zolpidem Tartrate, Zonisamide, Amlopidine Besylate Atorvastatin Calcium Salt

Interference:

The following compounds were shown to have no interference in the cocaine assay.

Atropine, Bupropion, Cotinine, Cannabinol, Chlorpheniramine maleate, O-Desmethylvenlafaxine, Desipiramine, Doxylamine Succinate, 1S, 2R Ephedrine, Anhydroecgonine methyl ester, Naproxen, Nicotine, Nortriptyline, Propoxyphen, R,mR-Pseudoephedrine, Thioridazine, Cis-Tramadol, Venlafaxine HCl, 8-(-)-11-nor-9-carboxy-delta-9 THC, 11-nor-9-carboxy-delta 9 THC,Amoxicillin, Propanolol, Promethazine, Phenmetrazine, Phendimetrazine, Benzocaine, Ecgonine, Metanephrin, Glutethimide, Meprobamate, Methyprylon, Carbamazepine, Diazepam, Nordiazepam, Oxazapam, Acetominophen, Caffeine, Dyphylline, Methaqualone, Theophylline, Amitryptiline, Dextromethorphan, Lidocaine, Methocarbamol, Nordoxepin, Pentazocine, Phenylephrine, Triamterene, Ethosuximde, α-Methyl-α-Propylsuccinimde, Metharbital, Barbital, Methsuximide, Phensuximide, N-Normethylsuximde, Mephenytoin, Ethotoin, Mephobarbital, PEMA, Phenobarbital, Methyl PEMA, 10, 11-Dihydrocarbamazepine, Primidone, Carbamazepine, 5,5-Diphenylhydantoin, 4-Methylprimidone, Glutethimide, Methaqualone, Chlorpromazine, Flurazepam, AM-2201, JWH-019, JWH-081, JWH-122, CP47, 497 (±), CP 47, 497 (±) C8 Homologue, HU-211, JWH-200, JWH-250, Acetominophen, Caffeine, Chlorpheniramine, Ibuprogen, Naproxen, R,R-(-)-Pseudoepedrine, Epinephrine (±), Metanephrine (±), Normetanephrine (±), Alprazolam, Cimetidine, Citalopram HBr, Clonazepam, Clopidogrel Bisulfate, Fluconazole, Hydorchlorothiazide, Lamotrigine, L-Thyroxine, Methylphenidate HCl, Omeprazole, Amlopidine Besylate, Atorvastatin Calcium Salt, Azithromycin Dihydrate, Bupivacaine HCl Monohydrate, Cetirizine Di-HCl, Dimenhydrinate, Lisinopril Dihydrate, Propanolol, Benzocaine, Metanephrin

Calibrator:

Psychemedics prepares calibrators and control materials using drug stocks purchased from a commercial vendor. Each lot of drug is received with its specific certificate of analysis. The commercially obtained stock is made into calibrators and controls to the desired concentrations. The concentrations are confirmed by LC/MS/MS.

Sample Shipping Stability During Storage:

Five cocaine positive samples remained positive after approximately 6 months in storage and after shipping twice coast-to-coast.

Recovery:

The hair sample preparation for the screening HEIA is a phosphate buffer extraction procedure. Recovery of cocaine in the method was shown on average to be at least 81% complete after 2 hours.

Cosmetic Treatments:

Ten cocaine-negative head hair samples were treated with perm, dye, shampoo and relaxer and the results compared to the same samples without treatments. In each case of the 10 samples treated with a type of cosmetic treatment, all samples remained negative after the treatments.

Seven cocaine-positive head hair samples were treated with perm, dye, shampoo and relaxer and the results compared to the same samples without the treatments. In each case, the samples remained positive after the treatments.

Comparison Studies:

Study 1:

Samples positive or negative for cocaine were identified using the Psychemedics cocaine microplate assay (k111925), and then tested with the test device, the Psychemedics HEIA for cocaine in hair. The test device (assay) has been validated using 215 individual hair samples collected anonymously from a workplace setting. One hundred and twenty-three negative samples and 92 positive samples were identified by the immunoassays.

The stored hair samples were then tested using Psychemedics' LC/MS/MS confirmatory assay, to compare the Psychemedics HEIA results with the washed LC/MS/MS results. The studies comparing the HEIA with washed LC/MS/MS documented the source of hair (head or body) and other demographics as available. The comparison of the Psychemedics Cocaine HEIA with washed LC/MS/MS is shown in the following tables.

Table 1. Comparison of Cocaine HEIA Screening Results with LC/MS/MS of Washed Samples

HEIA Result	LC/MS/MS Result, ng Cocaine/10 mg hair (% of cutoff calibrator)			
	< 2.50 (< 50% below cutoff)	2.50 – 4.99 (≥ 50% below cutoff to cutoff)	5.00 – 7.50 (cutoff to ≥ 50% above cutoff)	> 7.50 (> 50% above cutoff)
Positive	0	3	14	75
Negative	119	4	0	0

Discordant Results: Positive HEIA/Negative LC/MS/MS

Washing of hair before confirmation: exclusion of potential environmental contamination and/or sweat-derived drug from hair analysis results can result in APPARENT discordant results. Ingested drugs are present in perspiration, which settles on the hair and requires removal if the hair analysis result is to reflect amount of drug ingested rather than exposure to the sweat-derived drug. Drug could also be present as a result of environmental contamination (e.g., powder, smoke). Hair is not washed prior to screening, as it would not be reasonable to wash hundreds of negative hair samples; i.e., samples that are negative without washing. Thus, it is expected that the washing performed before LC/MS/MS confirmation of presumptive positives removes external drug and the confirmation results may then be lower than the screening may have predicted without the consideration of sweat-derived drug and/or drug from environmental contamination.

Table 2. Discordant Results Between HEIA and Washed LC/MS/MS			
Sample	HEIA Result	LC/MS/MS Result (ng Cocaine/10 mg hair)	Comment
1	POS	3.49	Samples are screened by HEIA without hair washing. LC/MS/MS is performed only after washing once with isopropanol, 3 times 30 minutes with 0.01 M phosphate buffer and 2 times with 0.01 M phosphate buffer for 60 minutes. Thus, it is expected that some samples will be negative by LC/MS/MS after washing.
2	POS	3.75	
3	POS	4.27	

Study 2:

An additional set of samples were identified using the Psychemedics cocaine microplate assay and the test device. These samples were tested using Psychemedics' LC/MS/MS confirmatory assay both with and without prior washing of the samples, to compare the Psychemedics HEIA results with unwashed LC/MS/MS results and washed LC/MS/MS results. The studies comparing the HEIA with unwashed and washed LC/MS/MS documented the source of hair (head or body) and other demographics as available. The comparison of the Psychemedics Cocaine HEIA with unwashed and washed LC/MS/MS is shown in the following tables.

Table 3. Comparison of Cocaine HEIA Screening Results with Unwashed Cocaine LC/MS/MS				
HEIA Result	LC/MS/MS Result, ng Cocaine/10 mg hair (% of cutoff calibrator)			
	< 2.50 (< 50% below cutoff)	2.50 – 4.99 (≥ 50% below cutoff to cutoff)	5.00 – 7.50 (cutoff to ≤ 50% above cutoff)	> 7.50 (> 50% above cutoff)
Positive	0	2	4	35
Negative	44	7	0	0

Table 4. Comparison of Cocaine HEIA Screening Results with Washed Cocaine LC/MS/MS				
HEIA Result	LC/MS/MS Result, ng Cocaine/10 mg hair (% of cutoff calibrator)			
	< 2.50 (< 50% below cutoff)	2.50 – 4.99 (≥ 50% below cutoff to cutoff)	5.00 – 7.50 (cutoff to ≤ 50% above cutoff)	> 7.50 (> 50% above cutoff)
Positive	0	2	8	31
Negative	48	3	0	0

Discordant Results: Positive HEIA/Negative LC/MS/MS

Two samples in the second study were positive by HEIA and Negative by unwashed and washed LC/MS/MS. Both samples confirmed within 15% of the LC/MS/MS cutoff when unwashed. After washing, both samples decreased in cocaine concentration.

Table 5. Discordant Results Between HEIA and Unwashed LC/MS/MS			
Sample	HEIA Result	LC/MS/MS Result (ng Cocaine/10 mg hair)	Comment
1	POS	4.43	Although samples 1 and 2 confirmed negative after screening positive, they confirmed within 15% of the 5 ng/10 mg cocaine LC/MS/MS cutoff.
2	POS	4.96	

Table 6. Discordant Results Between HEIA and Washed LC/MS/MS			
Sample	HEIA Result	LC/MS/MS Result (ng Cocaine/10 mg hair)	Comment
1	POS	3.75	Samples 1 and 2 confirmed negative after screening positive and washing before LC/MS/MS. Confirmation of these samples after washing found a decrease in cocaine concentration relative to the unwashed samples.
2	POS	4.27	

Table 7. Comparison of Unwashed and Washed Samples			
Sample #	Unwashed LC/MS/MS (ng Cocaine/10 mg hair)	Washed LC/MS/MS (ng Cocaine/10 mg hair)	Comment
1	4.43	3.75	Both samples 1 and 2 had a decrease in cocaine concentration after washing.
2	4.96	4.27	

Table 8. Unwashed and Washed Comparison Study Sample Characteristics							
	Hair Source		Gender		Hair Color		
	Head	Body	Male	Female	Brown	Black	Salt/Pepper
# of Samples	65	27	79	13	47	39	6

Conclusion:

The Psychemedics HEIA for cocaine in hair is substantially equivalent based on acceptable performance studies, including precision, specificity and interference (including cosmetic effects).