July 27, 2021

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

Re: K201326
Trade/Device Name: Psychemedics Homogeneous Enzyme Immunoassay for Opiates in Hair,
Psychemedics Homogeneous Enzyme Immunoassay for Oxycodone in Hair
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG
Dated: January 5, 2021
Received: January 6, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201326

Device Name
Psychemedics Homogeneous Enzyme Immunoassay for Opiates in Hair
Psychemedics Homogeneous Enzyme Immunoassay for Oxycodone in Hair

Indications for Use *(Describe)*
The Psychemedics homogeneous enzyme immunoassay (HEIA) for opiates in hair is an enzyme immunoassay for the preliminary qualitative detection of opiates in human head and body hair using a morphine calibrator at 2 ng morphine/10 mg hair for the purpose of identifying opiate use. This is an in vitro diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone. The Psychemedics homogeneous enzyme immunoassay for opiates in hair provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) is the preferred confirmatory method.

The Psychemedics homogeneous enzyme immunoassay (HEIA) for oxycodone in hair is an enzyme immunoassay for the preliminary qualitative detection of oxycodone in human head and body hair using an oxycodone calibrator at 2 ng oxycodone/10 mg hair for the purpose of identifying opioid use. This is an in vitro diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone. The Psychemedics homogeneous enzyme immunoassay for oxycodone in hair provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) is the preferred confirmatory method.

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.

510(k) Summary

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: k201326

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:	July 26, 2021
Device Trade Name:	Psychemedics Homogeneous Enzyme Immunoassay for Opiates in Hair Psychemedics Homogeneous Enzyme Immunoassay for Oxycodone in Hair
Predicate Device:	Psychemedics Microplate EIA for Opiates in Hair, k111926 and Psychemedics Microplate EIA for Oxycodone in Hair, k123799
Product Code:	DJG
Device/Classification Name:	21 CFR 862.3650 Opiate Test System, Classification II
Intended Use:	The Psychemedics homogeneous enzyme immunoassay (HEIA) for opiates in hair is an enzyme immunoassay for the preliminary qualitative detection of opiates in human head and body hair using a morphine calibrator at 2 ng morphine/10m mg hair for the purpose of identifying opiate use. This is an in vitro diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone. The Psychemedics homogeneous enzyme immunoassay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Liquid Chromatography/Mass

Spectrometry/Mass Spectrometry (LC/MS/MS) is the preferred confirmatory method.

The Psychemedics homogeneous enzyme immunoassay (HEIA) for oxycodone in hair is an enzyme immunoassay for the preliminary qualitative detection of oxycodone in human head and body hair using an oxycodone calibrator at 2 ng oxycodone/10 mg hair for the purpose of identifying opioid use. This is an in vitro diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone. The Psychemedics homogeneous enzyme immunoassay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) is the preferred confirmatory method.

Device Description:

The homogeneous enzyme immunoassay (HEIA) test consists of two parts; a pre-analytical hair treatment procedure (to extract opioids from the solid hair matrix to form a measurable liquid matrix) and the screening assay, the Psychemedics Opiates HEIA and the Psychemedics Oxycodone 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 Opiates HEIA consists of reagents R1 (anti-opiates monoclonal antibody with substrate) and R2 (morphine labeled recombinant G6PDH). The Psychemedics Oxycodone HEIA consists of reagents R1 (anti-oxycodone monoclonal antibody with substrate) and R2 (oxycodone 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 opiates in hair samples stored at room temperature has been shown for approximately 2 months. Opiates in samples shipped coast-to-coast twice was stable.

Materials Required: Hair sample HEIA for Opiates, HEIA for Oxycodone, automated clinical chemistry analyzer, LC/MS/MS for confirmation.

Comparison with Predicate:

Device & Predicate Device(s):	K201326	K111926
Device Trade Name	Psychemedics Homogeneous Enzyme Immunoassay for Opiates in Hair	Psychemedics Microplate EIA for Opiates in Hair
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Psychemedics homogeneous enzyme immunoassay (HEIA) for opiates is an enzyme immunoassay for the preliminary qualitative detection of opiates in human head and body hair using a morphine calibrator at 2 ng morphine/10 mg hair for the purpose of identifying opiate use. This is an in vitro diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone. The Psychemedics homogeneous enzyme immunoassay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) is the preferred confirmatory method.	The Psychemedics Microplate EIA for Opiates is an enzyme immunoassay (EIA) for the preliminary qualitative detection of opiates in human head and body hair samples using a morphine calibrator at 2 ng/10 mg hair cutoff for the purpose of identifying opiate use.
Sample Matrix	Human Hair	Same

General Device Characteristic Differences		
Method of Measurement	Automated Clinical Chemistry Analyzer at 340 nm	Microplate Reader at 450 nm
Antibody	Mouse monoclonal	Rabbit polyclonal

Device & Predicate Device(s):	K201326	K123799
Device Trade Name	Psychemedics Homogeneous Enzyme Immunoassay for Oxycodone in Hair	Psychemedics Microplate EIA for Oxycodone in Hair
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Psychemedics homogeneous enzyme immunoassay (HEIA) for oxycodone is an enzyme immunoassay for the preliminary qualitative detection of oxycodone in human head and body hair using an oxycodone calibrator at 2 ng oxycodone/10 mg hair for the purpose of identifying opioid use. This is an in vitro diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone. The Psychemedics homogeneous enzyme immunoassay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) is the preferred confirmatory method.	The Psychemedics Microplate EIA for Oxycodone is an enzyme immunoassay (EIA) for the preliminary qualitative detection of oxycodone in human head and body hair samples using an oxycodone calibrator at 2 ng/10 mg hair cutoff for the purpose of identifying oxycodone use.
Sample Matrix	Same	Human hair
General Device Characteristic Differences		
Method of Measurement	Automated Clinical Chemistry Analyzer at 340 nm	Microplate Reader at 450 nm
Antibody	Mouse monoclonal	Rabbit polyclonal

Performance Testing Summary:

Precision studies were performed by spiking negative hair with previously validated LC/MS/MS validated calibrator and control solutions to achieve concentrations of negative, the cutoff calibrator of 2 ng morphine/10 mg hair or 2 ng oxycodone/10 mg hair, and +/-75%, +/-50% and +/-25% of the cutoff calibrator. The results were identical for both immunoassays and are summarized below:

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 opiate structural analogs was evaluated by determining the minimum concentration that would result approximately equivalent to the 2.0 ng morphine/10 mg hair cutoff.

Opiates HEIA: Cross Reactivities of Structurally Related Compounds and Metabolites		
Compound	% Cross Reactivity	Concentration Equivalent to2.0 ng Morphine/10 mg Hair
Codeine	100	2.0
6-Acetylmorphine	80	2.5
Hydrocodone	20	10
Hydromorphone	13	15
Buprenorphine	10	20
Oxycodone	<2	>100
Oxymorphone	<2	>100

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

Lisinopril Dihydrate, Atropine, Bupropion, Cotinine, Cannabinol, Chlorpheniramine Maleate, O-Desmethylvenlafaxine, Desipramine, Doxylamine Succinate, 1S, 2R-Ephedrine, Amitriptyline, Dextromethorphan, Lidocaine, Methocarbamol, Nordoxepin,

Pentazocine, Phenylephrine, Triamterene, Naproxen, Nicotine, Nortriptyline, Propoxyphene, R,R- Pseudoephedrine, Thioridazine, Cis-Tramadol, Venlafaxine HCl, 8-(-)11-nor-9- carboxy-delta 9 THC, 11-nor-9-carboxy-delta 9 THC, Amoxicillin, Propranolol, Promethazine, Phenmetrazine, Phendimetrazine, Benzocaine, Dimenhydrinate, Carbamazepine, Diazepine, Nordiazepam, Oxazepam, Acetaminophen, Caffeine, Dyphylline, Methaqualone, Theophylline, Amphetamine, Cetirizine DiHCl, Imipramine, Methamphetamine, Phencyclidine, Phenylpropanolamine, Amitriptyline, Bupivacaine HCl, Lidocaine, Methocarbamol, Nordoxepin, Pentazocine, Phenylephrine, Triamterene, Ethosuximide, Alpha-methyl-alpha-propyl succinimide, Metharbital, Barbital, Methsuximide, Phensuximide, N-Normethsuximide, Mephyton, Ethotoin, Mephobarbital, PEMA, Phenobarbital, Methyl PEMA, 10, 11- Dihydrocarbamazepine, Primidone, 5,5-Diphenylhydantoin, 4-Methylprimidone, Butabarbital, Amobarbital, Secobarbital, Hexobarbital, Azithromycin 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, Lamotrigine, L-Thyroxine, Methylphenidate HCl, Omeprazole, Levetiracetam, Sertraline HCl, Topiramate, Zolpidem Tartrate, Zonisamide, Amlodipine Besylate Atorvastatin Calcium Salt.

The cross reactivity of the following metabolites, opioid structural analogs and the tricyclic antidepressant imipramine was evaluated by determining the minimum concentration that would result approximately equivalent to the 2.0 ng oxycodone/10 mg hair cutoff.

Oxycodone HEIA: Cross Reactivities of Structurally Related Compounds and Metabolites		
Compound	% Cross Reactivity	Concentration Equivalent to 2.0 ng Oxycodone/10 mg Hair
Hydrocodone	80	2.5
Codeine	67	3.0
6-Acetylmorphine	27	7.5
Morphine	27	7.5
Buprenorphine	13	15
Hydromorphone	10	20
Oxymorphone	5	40
Imipramine	2	100

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

Lisinopril Dihydrate, Atropine, Bupropion, Cotinine, Cannabinol, Chlorpheniramine Maleate, O-Desmethylvenlafaxine, Desipramine, Doxylamine Succinate, 1S, 2R-Ephedrine, Amitriptyline, Dextromethorphan, Lidocaine, Methocarbamol, Nordoxepin, Pentazocine, Phenylephrine, Triamterene, Naproxen, Nicotine, Nortriptyline, Propoxyphene, R,R- Pseudoephedrine, Thioridazine, Cis-Tramadol, Venlafaxine HCl, 8-(-)11-nor-9- carboxy-delta 9 THC, 11-nor-9-carboxy-delta 9 THC, Amoxicillin, Propranolol, Promethazine, Phenmetrazine, Phendimetrazine, Benzocaine, Dimenhydrinate, Carbamazepine, Diazepine, Nordiazepam, Oxazepam, Acetaminophen, Caffeine, Dyphylline, Methaqualone, Theophylline, Amphetamine, Cetirizine DiHCl, Methamphetamine, Phencyclidine, Phenylpropanolamine, Amitriptyline, Bupivacaine HCl, Lidocaine, Methocarbamol, Nordoxepin, Pentazocine, Phenylephrine, Triamterene, Ethosuximide, Alpha-methyl-alpha-propyl succinimide, Metharbital, Barbital, Methsuximide, Phensuximide, N-Normethsuximide, Mephenytoin, Ethotoin, Mephobarbital, PEMA, Phenobarbital, Methyl PEMA, 10, 11-Dihydrocarbamazepine, Primidone, 5,5-Diphenylhydantoin, 4-Methylprimidone, Butabarbital, Amobarbital, Secobarbital, Hexobarbital, Azithromycin 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, Lamotrigine, L-Thyroxine, Methylphenidate HCl, Omeprazole, Levetiracetam, Sertraline HCl, Topiramate, Zolpidem Tartrate, Zonisamide, Amlodipine Besylate, Atorvastatin Calcium Salt

Interference:

The following compounds were shown to have no interference in the opiates and oxycodone assay with the exception of imipramine. Imipramine was shown to be an interferent in the oxycodone and hydrocodone assay at a concentration of ≥ 100 ng imipramine/10 mg hair.

Atropine, Bupropion, Cotinine, Cannabinol, Chlorpheniramine maleate, O- Desmethylvenlafaxine, Desipramine, Doxylamine Succinate, 1S, 2R Ephedrine, Anhydroecgonine methyl ester, Naproxen, Nicotine, Nortriptyline, Propoxyphene, R,R-Pseudoephedrine, Thioridazine, Cis-Tramadol, Venlafaxine HCl, 8-(-)-11-nor-9-carboxy-delta-9 THC, 11-nor-9-carboxy-delta 9 THC, Amoxicillin, Propranolol, Promethazine, Phenmetrazine, Phendimetrazine, Benzocaine, Ecgonine, Glutethimide, Meprobamate, Methyprylon, Carbamazepine, Diazepam, Nordiazepam, Oxazepam, Acetaminophen, Caffeine, Dyphylline, Methaqualone, Theophylline, Amitriptyline, 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, Acetaminophen, Caffeine, Chlorpheniramine, Ibuprofen, Naproxen, R,R-(-)-Pseudoephedrine, Epinephrine (±), Metanephrine (±), Normetanephrine (±), Alprazolam, Cimetidine, Citalopram HBr,

	Clonazepam, Clopidogrel Bisulfate, Fluconazole, Hydorchlorothiazide, Lamotrigine, L-Thyroxine, Methylphenidate HCl, Omeprazole, Amlodipine Besylate, Atorvastatin Calcium Salt, Azithromycin Dihydrate, Bupivacaine HCl Monohydrate, Cetirizine Di- HCl, Dimenhydrinate, Lisinopril Dihydrate, Benzocaine.
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 and Stability During Storage:	Seven opiate positive samples remained positive after approximately two months in storage and after shipping twice coast-to-coast in the opiates HEIA. Six opioid positive samples remained positive after approximately five months in storage and after shipping twice coast-to-coast in the oxycodone and hydrocodone HEIA.
Recovery:	The hair sample preparation for the screening HEIA is an acidic phosphate buffer extraction procedure. Recovery of opiates in the opiates HEIA was shown on average to be at least 94% complete after 3 hours. Recovery of opioids in the oxycodone and hydrocodone HEIA was shown on average to be at least 85% complete after 3 hours.
Cosmetic Treatments:	Fifteen opiate-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 fifteen samples treated with a type of cosmetic treatment, all samples remained negative in the opiates HEIA after the treatments. Ten opiate-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 in the opiates HEIA after the treatments. Fifteen opioid-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 15 samples treated with a type of cosmetic treatment, all samples remained negative in

the oxycodone HEIA after the treatments.

Ten opioid-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 in the oxycodone HEIA after the treatments.

Comparison Studies: Samples positive or negative for opiates were identified using the Psychemedics opiates microplate assay (k111926), and then tested with the test device, the Psychemedics HEIA for opiates in hair. The test device (assay) has been validated using 230 individual hair samples collected anonymously from a workplace setting.

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

Opiates HEIA Result	**Washed LC/MS/MS Result, ng Morphine/10 mg hair (% of cutoff calibrator)**			
	< 1.0 (< 50% below cutoff)	1.0 – 1.99 (≥ 50% below cutoff to cutoff)	2.0 – 3.0 (cutoff to ≤ 50% above cutoff)	> 3.0 (> 50% above cutoff)
Positive	43	3	14	42
Negative	118	10	0	0

The presence of codeine, 6-AM, and morphine was detected by LC-MS/MS in the discordant results observed, and the presence of these analytes contributed to the positive results observed by the screening assay.

Samples positive or negative for opioids were identified using the Psychemedics oxycodone microplate assay (k123799) or opiates microplate assay (k111926), and then tested with the test device, the Psychemedics HEIA for oxycodone in hair. The test device (assay) has been validated using 219 individual hair samples collected anonymously from a workplace setting.

The stored hair samples were then tested using Psychemedics' LC/MS/MS confirmatory assay, to compare the Psychemedics HEIA results with the LC/MS/MS results. The studies comparing

the HEIA with LC/MS/MS documented the source of hair (head or body) and other demographics as available. The comparison of the Psychemedics Oxycodone HEIA with LC/MS/MS is shown in the following tables.

Oxycodone HEIA Result	**Washed LC/MS/MS Result, ng Oxycodone/10 mg hair (% of cutoff calibrator)**			
	< 1.0 (< 50% below cutoff)	1.0 – 1.99 (≥ 50% below cutoff to cutoff)	2.0 – 3.0 (cutoff to≤ 50% above cutoff)	> 3.0 (> 50% above cutoff)
Positive	48	8	15	31
Negative	103	14	0	0

The presence of hydrocodone was detected by LC-MS/MS in the discordant results observed, and the presence of this analyte contributed to the positive results observed by the screening assay.

Conclusion:

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

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