510 K SUMMARY

MAY 2 2013

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: k130811

Submitted By: Psychemedics Corporation

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Date Prepared: March 22, 2013

Device Trade Name: Psychemedics Microplate EIA for Amphetamine in Hair

Predicate Device: Cozart EIA Amphetamine Oral Fluid Microplate Kit, k033743

Product Code: DKZ

Device Classification/Name: 21 CFR 862.3100, Enzyme Immunoassay, Amphetamine; Classification II;

Intended Use: The Psychemedics Microplate EIA for Amphetamine is an enzyme immunoassay (EIA) for the preliminary qualitative detection of amphetamine in human head and body hair using an amphetamine calibrator at 3 ng /10 mg hair cutoff for the purpose of identifying amphetamine use. This is an *in vitro* diagnostic device intended exclusively for Psychemedics use only. Psychemedics has not performed an evaluation of reproducibility at different laboratories.

The Psychemedics Microplate EIA amphetamine 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 or Liquid Chromatography/Double Mass Spectrometry (GC/MS or LC/MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Assay Description: The test consists of two parts; a **pre-analytical** hair treatment procedure (to convert the solid matrix of hair to a measurable liquid matrix) and the **screening assay**, the Psychemedics Microplate EIA for Amphetamine. The screening portion of the test system consists of (1) microplate wells coated with multiple antigens including methamphetamine conjugated to bovine serum albumin (BSA), monoclonal mouse anti-amphetamine, rabbit anti-mouse secondary antibody conjugated to HRP (horseradish peroxidase), substrate [3, 3', 5, 5' tetramethylbenzidine (TMB)], HCl to

acidify (and stop the reaction), and wash buffer for washing the plates. Absorbance in the wells is read with a microplate reader.

Sample Collection & 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 amphetamine in hair samples stored at room temperature has been shown for at least one year. Amphetamine in samples shipped coast-to-coast twice was stable.

Materials required: Hair sample collection kit, Microplate EIA for Amphetamine, Microplate washer and reader, LC/MS/MS for confirmation.

Comparison with Predicate:

Item	Proposed Device	Cozart EIA Amphetamines Oral Fluid Microplate Kit
Indications/ Intended use	The Psychemedics Microplate EIA for Amphetamine is an enzyme immunoassay (EIA) for the preliminary qualitative detection of amphetamine in human head and body hair using an amphetamine calibrator at 3 ng /10 mg hair cutoff for the purpose of identifying amphetamine use. The Psychemedics Microplate EIA amphetamine 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 or Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (GC/MS or LC/MS/MS) is the preferred confirmatory method.	Cozart EIA Amphetamines Oral Fluid Microplate Kit is a qualitative test for amphetamine in oral fluid. It is intended for qualitative detection of amphetamine in human oral fluid at 100 ng/mL. The test is intended for professional use. It is not intended for over-the-counter sales to non-professionals. It provides only preliminary analytical test results. A more specific alternate chemical method must be used in order to obtain a confirmed result. GC/MS is the preferred confirmatory method.
Product Code	DKZ	DKZ
Measurand	Amphetamine in Hair	Amphetamine in Oral Fluid
Test System	Psychemedics EIA for Amphetamine in Hair	Cozart EIA Amphetamines Oral Fluid Microplate Kit
Sample Matrix	Human Hair	Human Oral Fluid
Method of Measurement	Microplate reader, read at 450 nm	Microplate reader, read at 450 nm
Cutoff	3 ng amphetamine/10 mg hair (300 pg amphetamine /mg hair)	100 ng amphetamine/mL oral fluid

Type of Test	Enzyme Immunoassay	Enzyme Immunoassay
Extraction Method	Patented Digestion method	Not applicable
Confirmation Method	LC/MS/MS	GC/MS

Summary of Performance Testing

The precision studies were performed by spiking negative hair with previously LC/MS/MS-validated calibrator and control spiking solutions to achieve concentrations of negative, the cutoff of 2 ng/10 mg hair, and +/-75%, +/-50%, and +/- 25% of the cutoff.

Precision Studies

Summary -Intra-Assay				Summary-Inter-Assay		
LEVEL	NEG	POS		LEVEL	NEG	POS
B_0 (-100%)	15	0		**B_0 (-100%)**	75	0
-75%	15	0		**-75%**	75	0
-50%	15	0		**-50%**	75	0
-25%	15	0		**-25%**	75	0
plus 25%	0	15		**plus 25%**	0	75
plus 50%	0	15		**plus 50%**	0	75
plus 75%	0	15		**plus 75%**	0	75
plus 100%	0	15		**plus 100%**	0	75

ComparisonTesting

One hundred eighty samples comprising both head and body hair were confirmed by LC/MS/MS in parallel with testing by the Psychemedics Amphetamine EIA, with the results shown in the following table.

The studies comparing the EIA with LC/MS/MS documented the age, gender and ethnicity of subjects, hair color, and source of hair (body or head hair).

Amphetamine EIA Test Result	Negative by GC/MS	Less than half the cutoff concentration by GC/MS	Near Cutoff Negative (Between 50% below the cutoff and the cutoff)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff)	High Positive (Greater than 50% above the cutoff)
Positive	14	2	17	22	59
Negative	38	17	11	0	0

Discordant Results of Comparison Testing

Screening Cutoff (ng/10 mg hair)	Amphetamine EIA Result (POS/NEG)	LC/MS/MS Drug Result (ng/ 10 mg hair)
3	POS	0 amphetamine, 16 phentermine
3	POS	0 amphetamine, 16 phentermine
3	POS	0 amphetamine, 17 phentermine
3	POS	0 amphetamine, 18 phentermine
3	POS	0 amphetamine, 19 phentermine
3	POS	0 amphetamine, 23 phentermine
3	POS	0 amphetamine, 23 phentermine
3	POS	0 amphetamine, 23 phentermine
3	POS	0 amphetamine, 40 phentermine
3	POS	0 amphetamine, 44 phentermine
3	POS	0 amphetamine, 49 phentermine
3	POS	0 amphetamine, 55 phentermine
3	POS	0 amphetamine, 65 phentermine
3	POS	0 amphetamine, 86 phentermine
3	POS	1.2 amphetamine, 9.6 methamphetamine
3	POS	1.3 amphetamine, 21.8 methamphetamine
3	POS	1.4 amphetamine, 21 methamphetamine
3	POS	2.0 amphetamine, 20.6 methamphetamine
3	POS	2.1 amphetamine, 39.8 methamphetamine
3	POS	2.6 amphetamine, 31.7 methamphetamine
3	POS	2.8 amphetamine, 24.1 methamphetamine
3	POS	1.6 amphetamine, 27.8 methamphetamine
3	POS	1.6 amphetamine, 31 methamphetamine
3	POS	1.7 amphetamine, 15.6 methamphetamine
3	POS	2.0 amphetamine, 31 methamphetamine
3	POS	2.1 amphetamine, 25 methamphetamine
3	POS	2.2 amphetamine, 26.8 methamphetamine
3	POS	2.6 amphetamine, 10.8 methamphetamine
3	POS	2.5 amphetamine, 14.2 methamphetamine
3	POS	2.5 amphetamine, 49.8 methamphetamine
3	POS	2.7 amphetamine, 41.9 methamphetamine
3	POS	2.8 amphetamine, 32.6 methamphetamine
3	POS	1.7 amphetamine, 17.5 methamphetamine

Cosmetic Treatments

Twenty amphetamine-negative head hair samples were treated with bleach, 20 with permanent wave, 20 with dye, 20 with relaxer, and 20 with shampoo, and the results compared to the same samples without the treatments. In each case of the 20 samples treated with a type of cosmetic treatment, 10 samples were treated with one brand of a particular product and 10 other samples with a second brand. No significant differences in EIA results were observed for the negative hair samples before and after the treatments; all samples remained negative after the treatments.

Twelve amphetamine-positive head hair samples were treated with bleach, permanent wave, dye, relaxer, and shampoo, and the results compared to the same samples without the treatments. In each case of samples treated with a type of cosmetic treatment, 6 samples were treated with one brand of a particular product and 6 other samples with a second brand. None of the samples became negative, by either EIA or LC/MS/MS, after treatment with any of the cosmetic products.

Summary of Cross-reactivity and Interference Studies

Chloramphetamine, MDA, PMA and Phentermine showed significant cross-reactivity in the amphetamine EIA. One-hundred-forty other compounds showed no cross-reactivity in the assay. One-hundred-nineteen compounds tested for interference at +/-50% of the cutoff showed no interference in the assay.

Cross-reactivity of related Compounds in Amphetamine EIA

Compound	Percent Cross-reactivity*	Expected Concentration Equivalent to 3 ng Amphetamine/10 mg hair
MDA	120	2.5
d-amphetamine	100	3.0
PMA	100	3.0
Chloramphetamine	79	3.8
Phentermine	17.6	17
l-amphetamine	1.1	270
MDMA	0.5	600
PMMA	0.5	600
Phenylpropanolamine	< 0.3	>1000
Pseudoephedrine	< 0.3	>1000
1R, 2S Ephedrine	< 0.3	>1000
S,S Pseudoephedrine	< 0.3	>1000
Phenylethylamine	< 0.3	>1000
MDEA	< 0.3	>1000
L-methamphetamine	< 0.3	>1000
Ranitidine	< 0.3	>1000
Fenfluramine	< 0.3	>1000
Mephentermine	< 0.3	>1000
Phenmetrazine	< 0.3	>1000
Phendimetrazine	< 0.3	>1000
Metanephrin	< 0.3	>1000

Environmental Contamination

Aqueous Washing of Samples Soaked in Water and Saline Solutions of Amphetamine

Contamination of head hair samples by soaking in 500 ng amphetamine /mL of water resulted in a range of amphetamine on the hair of 7.9 – 225.8 ng of amphetamine /10 mg hair before washing. After washing by the procedure described below, the amount of oxycodone remaining on the hair samples ranged from 0.6 to 76.3/10 mg hair, with 8 of the 11 samples appearing to be positive before application of the wash criterion. After application of the wash criterion, all of these samples containing amphetamine above the cutoff were determined to be contaminated (not positive).

Contamination of head hair samples by soaking in 500 ng amphetamine/mL of saline resulted in a range of amphetamine on the hair of 2.3 – 42.8 ng of amphetamine /10 mg hair before washing. After washing by Psychemedics hair washing procedure (below), the amount of amphetamine remaining on the hair samples ranged from 0.5 to 9.5 ng/10 mg hair, with 10 of 11 samples below the cutoff even without application of the wash criterion. The one sample that was above the cutoff was determined to be negative by the wash criterion.

The Aqueous Buffer Wash Procedure

a. Wash by Psychemedics' standard wash procedure:
   i. Add 2 mL of dry isopropanol and shake in waterbath for 15 minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove isopropanol.
   ii. Add 2 mL of Wash Buffer (0.01 M phosphate buffer, pH 6.0, containing 0.1% BSA) and shake in waterbath for 30 minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove Buffer.
   iii. Repeat Step ii. two more times.
   iv. Add 2 mL of Wash Buffer, and shake in waterbath for 60 minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove Buffer.
   v. Repeat Step iv. one more time. Remove Buffer and save for analysis. Hair samples are now ready for digestion and extraction for LC/MS/MS analysis

4. Contamination Results for Amphetamine

Abbreviations used in the tables below: Hair Color: BLK, black; BRN, brown; LT, light; DK, dark; BLND, Blond. Ethnicity: As, Asian; Af-Am, African American; H, Hispanic; Ca, Caucasian; Curvature: S, straight; C, curly.

Contamination of Hair in 500 ng Amphetamine/mL Water—Aqueous Buffer Wash

Sample #	Color	Curvature, Ethnicity	Total Drug on Hair*	Drug in Hair after Washing**	Drug in Last Wash	Apply Wash Criterion***	POS/ NEG	P, porous; VP, very porous; N, normal
			ng amphetamine/10 mg hair					
1	MED BRN	S, Ca	35.1	5.98	39.07	-130.77	NEG	VP
2	DK BRN	S, H	225.8	76.36	253.38	-810.47	NEG	VP
3	BLK	S, As	7.97	2.68	8.80	NA	NEG	N
4	DK BRN	S, H	19.35	3.64	18.75	-61.99	NEG	N
5	MED BRN	S, Ca	13.03	3.52	14.34	-46.67	NEG	N
6	MED BRN	S, Ca	26.66	3.11	21.10	-70.74	NEG	P
7	LT BRN	S, Ca	23.58	5.36	21.49	-69.86	NEG	N
8	LT BRN	S, Ca	30.82	5.65	37.30	-124.90	NEG	P
9	BLK	C, Af Am	3.40	0.67	4.06	NA	NEG	N
10	BLND	S, Ca	2.71	0.75	1.96	NA	NEG	N
11	BLND	S, Ca	72.6	5.93	49.41	-167.01	NEG	P

*Total Amphetamine found by LC/MS/MS with unwashed hair samples.
**Wash Criterion: Hair – (3.5 x Last Wash); if Wash Criterion result is < 3.0, the result is due to contamination.

Contamination of Hair in 500 ng Amphetamine/mL Saline -- Aqueous Buffer Wash

Sample #	Color	Curvature, Ethnicity	Total Drug on Hair*	Drug in Hair after Washing	Drug in Last Wash	Apply Wash Criterion**	POS/ NEG	P, porous; VP, very porous; N, normal
			ng amphetamine/10 mg hair					
1	BRN	S, Ca	2.85	0.50	2.77	NA	NEG	P
2	MED BRN	S, Ca	6.63	1.48	5.19	NA	NEG	VP
3	BLK	S, As	2.13	0.95	1.31	NA	NEG	VP
4	DK BRN	S, H	7.71	1.45	6.70	NA	NEG	N
5	MED BRN	S, Ca	3.38	1.34	2.69	NA	NEG	N
6	MED BRN	S, Ca	3.91	1.06	4.32	NA	NEG	P
7	LT BRN	S, Ca	6.65	2.09	9.61	NA	NEG	P
8	BLND	S, Ca	22.81	9.51	20.56	-62.45	NEG	N
9	BLK	C, AfAm	2.38	0.69	2.63	NA	NEG	N
10	BLND	S, Ca	3.22	0.76	3.0	NA	NEG	N
11	BLND	S, Ca	10.36	1.36	6.79	NA	NEG	P

*Total Amphetamine found by LC/MS/MS with unwashed hair samples.
**Wash Criterion: Hair – (3.5 x Last Wash); if Wash Criterion result is < 3.0, the result is due to contamination.

An Alternative Wash Procedure

Studies were performed on an alternative washing method for porous samples that may lose some drug from ingestion when subjected to aqueous wash procedures. The alternative wash procedure for porous samples consists of a series of 90% ethanol washes: three 30-minute washes and two 60-minute washes. The last wash is analyzed and the value obtained is used to determine a wash criterion. The wash criterion is the result of the multiplication of the last wash drug content by 3.5 and subtraction of this value from the drug content of the hair. If the result of the subtraction falls below the cutoff, the sample is interpreted as negative or contaminated, not positive.

For 10 head hair samples soaked in a water solution of 500 ng/mL amphetamine, after washing by the alternative ethanol procedure, the amount of amphetamine remaining on the hair samples ranged from 2.2 to 140.1 ng/10 mg hair, with 9 of the 10 samples appearing to be positive before application of the wash criterion. After application of the wash criterion, all of these samples containing amphetamine above the cutoff were determined to be contaminated (not positive).

For 13 head hair samples soaked in a saline solution of 500 ng/mL amphetamine, after washing by the alternative ethanol procedure, the amount of amphetamine remaining on the hair samples ranged from 0.9 to 14.7 ng/10 mg hair, with 8 of 13 samples below the cutoff even without application of the wash criterion. The 5 samples above the cutoff were determined to be negative by the wash criterion.

Contamination of Hair in 500 ng Amphetamine/mL Water—90% Ethanol Wash

Sample #	Color	Curvature, Ethnicity	Total Drug on Hair*	Drug in Hair after Washing	Drug in Last Wash	Apply Wash Criterion**	POS/ NEG	P, porous; VP, very porous; N, normal
			ng amphetamine/10 mg hair					
1	BRN	S, Ca	2.85	1.43	0.33	NA	NEG	P
2	MED BRN	S, Ca	6.63	3.44	1.47	-1.71	NEG	VP
3	DK BRN	S, H	13.67	8.24	1.86	1.73	NEG	VP
4	BLK	S, As	2.13	0.93	0.22	NA	NEG	N
5	DK BRN	S, H	7.71	3.58	0.80	0.78	NEG	N
6	MED BRN	S, Ca	3.38	2.29	0.25	NA	NEG	N
7	MED BRN	S, Ca	3.91	2.42	0.65	NA	NEG	P
8	LT BRN	S, Ca	1.91	1.16	0.29	NA	NEG	N
9	LT BRN	S, Ca	6.65	2.45	1.81	NA	NEG	P
10	BLND	S, Ca	22.81	14.77	5.31	-3.82	NEG	N
11	Af-Am	C, AfAm	2.38	1.45	0.31	NA	NEG	N
12	BLND	S, Ca	3.22	0.94	0.57	NA	NEG	N
13	BLND	S, Ca	10.36	3.45	1.72	-2.57	NEG	P

*Total Amphetamine found by LC/MS/MS with unwashed hair samples.
**Wash Criterion: Hair – (3.5 x Last Wash); if Wash Criterion result is < 3.0, the result is interpreted as possibly due to external contamination with amphetamine.

Contamination of Hair in 500 ng Amphetamine/mL Saline—90% Ethanol Wash

Sample #	Color	Curvature, Ethnicity	Total Drug on Hair*	Drug in Hair after Washing	Drug in Last Wash	Apply Wash Criterion**	POS/ NEG	P, porous; VP, very porous; N, normal
			ng amphetamine/10 mg hair					
1	BRN	S, Ca	2.85	1.43	0.33	NA	NEG	P
2	MED BRN	S, Ca	6.63	3.44	1.47	-1.71	NEG	VP
3	DK BRN	S, H	13.67	8.24	1.86	1.73	NEG	VP
4	BLK	S, As	2.13	0.93	0.22	NA	NEG	N
5	DK BRN	S, H	7.71	3.58	0.80	0.78	NEG	N
6	MED BRN	S, Ca	3.38	2.29	0.25	NA	NEG	N
7	MED BRN	S, Ca	3.91	2.42	0.65	NA	NEG	P
8	LT BRN	S, Ca	1.91	1.16	0.29	NA	NEG	N
9	LT BRN	S, Ca	6.65	2.45	1.81	NA	NEG	P
10	BLND	S, Ca	22.81	14.77	5.31	-3.82	NEG	N
11	Af-Am	C, AfAm	2.38	1.45	0.31	NA	NEG	N
12	BLND	S, Ca	3.22	0.94	0.57	NA	NEG	N
13	BLND	S, Ca	10.36	3.45	1.72	-2.57	NEG	P

*Total Amphetamine found by LC/MS/MS with unwashed hair samples.

**Wash Criterion: Hair – (3.5 x Last Wash); if Wash Criterion result is < 3.0, the result is interpreted as possibly due to external contamination with amphetamine.

Storage and Shipping Stability

Twenty-one amphetamine-positive head hair samples were tested before and after 1 year of storage under ambient conditions. The average of the results after one year was 109% of the average of the original results. Twenty-one amphetamine-positive head hair samples were also tested before and after two coast-to-coast shippings. The samples after shipping had average results of 105% of the results of the samples before shipping.

Stability of Calibrator and Control Solutions

Psychemedics manufactures 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 the calibrators and controls to the desired concentrations. The concentrations are confirmed by LC/MS/MS. Stability of the amphetamine calibrator and control solutions was shown to be 9 months, with ongoing studies to demonstrate 1-year stability.

Recovery

Recovery of amphetamine from hair in a 2-hour incubation ranged from 100 to 110%. This was determined by LC/MS/MS measurements of extended sequential hair extractions.

Conclusion:

Comparison of results of the Psychemedics Microplate EIA for Amphetamine in Hair with LC/MS/MS confirmation showed the results to be substantially equivalent. The Psychemedics Microplate EIA for Amphetamine in Hair is substantially equivalent to the predicate, based on acceptable performance studies, including precision, specificity, interference (including cosmetic effects), and removal of external contamination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2013

Psychemedics Corp.
C/O Virginia Hill
5832 Uplander Way
CULVER CITY CA 90230

Re: K130811
Trade/Device Name: Psychemedics Microplate EIA for Amphetamine in Hair
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: DKZ
Dated: March 22, 2013
Received: March 25, 2013

Dear Ms. Hill:

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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S 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

Indications for Use

510(k) Number (if known): k130811

Device Name: Psychemedics Microplate EIA for Amphetamine in Hair

Indications for Use:

The Psychemedics Microplate EIA for Amphetamine is an enzyme immunoassay (EIA) for the preliminary qualitative detection of amphetamine in human head and body hair using an amphetamine calibrator at 3 ng /10 mg hair cutoff for the purpose of identifying amphetamine use. This is an in vitro diagnostic device intended exclusively for Psychemedics use only. Psychemedics has not performed an evaluation of reproducibility at different laboratories.

The Psychemedics Microplate EIA amphetamine 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 or Liquid Chromatography/Mass Spectrometry (GC/MS or LC/MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Psychemedics plans to perform this test at one site. Psychemedics has not performed an evaluation of reproducibility at different sites.

Prescription Use _____ And/Or Over the Counter Use __X__.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-Tyler-S
2013.05.01 15:53:34 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130811