510K SUMMARY

MAY - 1 2012

510K Number:	k111929
Submitted By:	Psychemedics Corporation 5832 Uplander Way Culver City, CA 90230 TEL: 310 216 7776 FAX: 310 216 6662
Submission Contact:	Virginia Hill
Date Prepared:	April 25, 2012
Device Trade Name:	Psychemedics Chemiluminescent Microplate EIA for Cannabinoids in Hair
Predicate Device:	Psychemedics Marijuana Screening and Confirmatory Test System
Product Code:	LDJ
Device Classification/Name:	21 CFR 862.3870, Enzyme Immunoassay, Cannabinoids; Classification II;
Intended Use:	The Psychemedics Microplate EIA for Cannabinoids in Hair is an enzyme immunoassay (EIA) for the preliminary qualitative detection of cannabinoids in human head and body hair samples using a 11-nor-9-Carboxy- Δ^9-THC calibrator at 10 pg/10 mg hair cutoff for the purpose of identifying marijuana use. This is an *in vitro* diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone. The Psychemedics Chemiluminscent Microplate EIA for Cannabinoids 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 Chromatography/Mass Spectrometry/Mass Spectrometry (GC/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 EIA screening test consists of two parts; a **pre-analytical** hair treatment procedure to recover the cannabinoids from the hair and the **screening assay**, the Psychemedics Chemiluminescent EIA for Cannabinoids in Hair. The device comprises a white microplate coated with the antigen (11-nor-9-carboxy-delta-8-tetrahydrocannabinol) conjugated to BSA, polyclonal rabbit anticannabinoid antibody, goat anti-rabbit secondary antibody conjugated to HRP (horseradish peroxidase), a chemiluminescent substrate, and plate-washing buffer.

Sample Collection: 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.

Materials required: Hair sample collection kit, Chemiluminescent Microplate EIA for Cannabinoids, Microplate washer and reader, GC/MS/MS for confirmation.

Comparison of Psychemedics Chemiluminescent Microplate EIA for Cannabinoids with Psychemedics Marijuana Screening and Confirmatory Test System

Item	Device	Predicate
Indications for Use	The Psychemedics Microplate EIA for Cannabinoids in Hair is an enzyme immunoassay (EIA) for the preliminary qualitative detection of cannabinoids in human head and body hair samples using a 11-nor-9-Carboxy- Δ^9-THC calibrator at 10 pg/10 mg hair cutoff for the purpose of identifying marijuana use. This is an *in vitro* diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone. The test is not intended for over the counter sale to non-professionals. The Psychemedics Chemiluminscent Microplate EIA for Cannabinoids 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 Chromatography/Mass Spectrometry/Mass Spectrometry (GC/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.	The Psychemedics Marijuana Screening and Confirmatory Test System is a bipartite device employing radioimmunoassay (RIA) for qualitative screening and mass spectrometry for confirmation and the final quantitative reporting of carboxy-THC in human hair samples at concentrations at or above 1 pg carboxy-THC/10 mg hair for the purpose of determining marijuana use. This product is intended exclusively for in-house professional use only. The test is not intended for over the counter sale to nonprofessionals. Clinical consideration and professional judgment should be applied to any drug of abuse test result.
510k	K111929	K011426
Measurand	Carboxy-THC /Cannabinoids	Carboxy-THC /Cannabinoids
Matrix	Human head or body hair	Human head or body hair
Cutoff	10 pg carboxy-THC/10 mg hair	20 pg carboxy-THC/10 mg hair

Type of Test	Enzyme Immunoassay	Radioimmunoassay
Method of Measurement	Microplate reader	Gamma Counter
Extraction Method	Acidic Extraction	Proteolytic Digestion
Confirmation	GC/MS/MS	GC/MS/MS

Summary of Performance Testing

Summary of Precision Studies

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

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

Agreement Testing

Six-hundred-ten hair samples were assayed by the predicate device and by the Psychemedics Methamphetamine EIA. The number of body hair samples in the study was 18.9% of the total hair samples. The discordance between EIA and RIA was < 1%.

	Negative by Predicate	**Positive by Predicate**
EIA Positive	4	189
EIA Negative	415	2

Three-hundred-eighteen of the samples were confirmed by LC/MS/MS, with the results shown in the following table.

GC/MS/MS:	Negative	≥ -50% of Cutoff and < Cutoff	≥ Cutoff and < +50% of Cutoff	≥ +50% Cutoff and < 100% of Cutoff	≥ +100% of cutoff
EIA Positive	0	5	1	7	176
EIA Negative	127	0	1	0	1

Cosmetic Treatment

Twenty cannabinoid-negative 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 were observed for the negative hair samples before and after the treatments; all negative samples remained negative after the treatments.

Twelve cannabinoid-positive hair samples were treated with bleach, 12 with permanent wave, 12 with dye, 12 with relaxer, and 12 with shampoo, and the results compared to the same samples without the treatments. In each case of the 12 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. The average of the EIA B/B_0 x 100 values obtained for the 12 positive samples in each set before treatment is shown, with the range following in parenthesis. In the second row of the table, the average of the EIA B/B_0 x 100 values obtained for the samples in each set after treatment is shown, with the range following in parenthesis. No positive samples became negative in the EIA after the cosmetic treatments.

Treatment Status	Bleach	Dye	Perm	Relaxer	Shampoo
	Mean (Range) of B/B_0 x 100 Values of 12 Cannabinoid-Positive Samples in Cannabinoid EIA				
Before	34.4 (18.2 – 54.8)	27.3 (7.9 – 54.8)	41.6 (24.8 – 61.6)	31.4 (7.9 – 63.3)	27.9 (7.9 – 54.8)
After	32.7 (10.6 – 59.6)	30.7 (13.0 – 57.3)	43.4 (20.9 – 65.4)	33.1 (13.2 – 62.2)	32.8 (15.7 – 55.1)

Contamination Study

Potential environmental contamination of samples that are identified as presumptive positive in the screening assay is addressed by GC/MS/MS confirmation analysis for the Carboxy-THC metabolite and an extensive washing procedure prior to confirmation.

Twelve hair samples ranging in color from light brown to black, with one red hair, were contaminated with smoke from a marijuana cigarette. Two days after the exposure the unwashed samples were analyzed by the Cannabinoid EIA assay and by GC/MS/MS for THC and Carboxy-THC. All of these smoke-contaminated samples were positive in the Chemiluminescent Microplate EIA for Cannabinoids. No carboxy-THC was present on the hair samples using the laboratory's standard GC/MS/MS procedure, while the THC on the samples ranged from 189 – 788 ng/10 mg hair. In a report by Wilkins et al., levels of THC on unwashed hair of proven marijuana users ranged from 0.3 – 10.6 ng/10 mg hair, 2-3 orders of magnitude less than the THC contamination achieved in this experiment (J. Anal. Toxicol. 19:483, 1995)

The same smoke-contaminated samples were also washed by our standard wash procedure for marijuana presumptive positive samples, to test whether carboxy-THC could be formed during the wash procedure. No carboxy-THC was detected in the THC-contaminated samples also subjected to the wash procedure.

The same smoke-contaminated samples were also soaked for 30 minutes in water or for 30 minutes in saline, and then carried through the wash, extraction, and GC/MS/MS procedures. These saline-soaked or water-soaked samples tested positive in the EIA Cannabinoids Assay. No carboxy-THC was detected by GC/MS/MS in the THC-contaminated samples soaked in saline or water.

Wash Procedure for Cannabinoids-Presumptive Positive Samples

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

Summary of Cross-reactivity and Interference Studies

Cross-reactivity of sixty-seven compounds was investigated. Seventy-five compounds were tested for interference at +/-50% of the cutoff showed no interference in the assay. The studies demonstrated the Cannabinoid EIA to be substantially equivalent with the predicate.

Stability of Calibrator and Control Solutions

The carboxy-THC calibrator and control solutions are prepared in-house by the laboratory from certified standards. Stability in methanol was shown for 1 year.

Recovery Study

Recovery of cannabinoids from hair of marijuana users was shown to be substantially equivalent to that of the predicate device.

Conclusion:

The Psychemedics Chemiluminescent Microplate EIA for Cannabinoids in Hair is substantially equivalent to the predicate device k011426, and the results are substantially equivalent to GC/MS/MS results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

PSYCHEMEDICS CORP.
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MAY - 1 2012

Re: k111929
Trade Name: PSYCHEMEDICS MICROPLATE EIA FOR CANNABINOIDS IN HAIR
Regulation Number: 21 CFR §862.3870
Regulation Name: Cannabinoid Test System
Regulatory Class: Class II
Product Codes: LDJ
Dated: March 9, 2012
Received: March 12, 2012

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number : k111929

Device Name: Psychemedics Microplate Chemiluminescent EIA for Cannabinoids in Hair

Indications For Use:

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Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use __X__ (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 Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111929