MAY 0 3 2002

Psychemedics Marijuana Screening and Confirmatory Test System

510(k) SUMMARY [K011426]

I. GENERAL INFORMATION

A.

Submitter's Name:	Psychemedics Corporation
Address:	5832 Uplander Way, Culver City, California 90230
Telephone Number:	(310) 216-7776; (800) 522-7424
Contact Person:	William R. Thistle, JD
Date prepared:	1st May 2002

B.

Device Generic Name:	Analytical Service: Marijuana Assay
Proprietary Name:	Psychemedics Marijuana Assay
Classification Name:	91 LAT (Toxicology) **CFR 862.3870**

Product Codes of Devices to Which Equivalence is Claimed: Dade Behring (K993984)

II. INTENDED USE

The Psychemedics Marijuana Assay 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 C-THC/10 mg hair for the purposes 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 non-professionals. Clinical consideration and professional judgement should be applied to any drug of abuse test result.

III. DESCRIPTION OF THE PRODUCT

The Psychemedics RIA Marijuana Screening Assay is based upon the competitive binding of ^{125}I-radiolabeled 11-nor-9-carboxy-Δ^8-THC and unlabeled marijuana use surrogates in proportion to their relative concentrations in the reaction mixture. An 8 mg specimen of hair is digested in a solution containing dithiothreitol and proteinase K at pH 9.5 for two hours. After the 2-hour digestion, the digest solution is neutralized, vortexed, and centrifuged to remove the melanin. Any remaining undigested hair strands may be removed, prior to centrifugation, with applicator sticks. An aliquot of hair digest equivalent to 5 mg is pre-treated by a patented procedure using DEAE Sephadex anion exchange resin to remove universally occurring cross-reactants. An aliquot of the resin-treated hair digest is then incubated with primary antibody (sheep anti-cannabinoids) and a fixed amount of radio-labeled 11-nor-9-carboxy-Δ^8-THC. The bound and free fractions are then separated by incubation with Second Antibody (rabbit anti-sheep), addition of polyethylene glycol, centrifugation and finally, decanting of the supernatant. The pellets containing the antigen-antibody complex are counted in a gamma scintillation counter. The calibrators and B_0 tubes are prepared by digesting 0.16 mg of BSA in 1.6 mL digest, carrying these along with unknown samples through digestion, neutralization and resin treatment, and then spiking the calibrators with 5 pg 11-nor-9-carboxy-Δ^9-tetrahydrocannabinol (carboxy-THC). Controls are prepared by spiking negative hair before digestion with aliquots of pre-digested known-marijuana-positive hair sample. A presumptive positive hair sample digest is one with a %B/Bo less than or equal to the cutoff standard containing 5 pg (equivalent to 20 pg/10 mg hair) 11-nor-9-carboxy-Δ^9-tetrahydrocannabinol (carboxy-THC).

Presumptive positives by RIA are confirmed and quantified by gas chromatography mass spectrometry mass spectrometry (GC/MS/MS) using dual derivatization isotope dilution negative ion chemical ionization techniques.

A comparison of hair analysis with the predicate device, Dade Behring's EMIT urine assay, is shown in Section VI.

IV. PRECAUTIONS AND WARNINGS

This assay was evaluated using primarily head hair samples from a population of drug abusers in treatment programs. Interpretation of results must take into account that drug concentrations detected in hair from a single individual can vary extensively depending on the site of collection. Positive RIA screening results only indicate the presumptive use of marijuana, and are subsequently analyzed by mass spectrometry to obtain a confirmed quantitative reporting result for carboxy-THC. A negative screening test result does not necessarily rule out the possibility of marijuana use, i.e., time of collection, frequency of use, mode of ingestion, dosage used, hair types and other factors may influence results. It is not possible to document all possible effects due to treatments such as bleaching, straightening and dyeing. There is a possibility that other substances and/or factors not listed above may produce incorrect RIA screening test results. However, false positive screen results would fail to be confirmed by mass spectrometry.

V. EQUIVALENCE COMPARISON

	Dade Behring EMIT(K993984)	**Psychemedics Marijuana Screening and Confirmatory Test System**
Type of Product	Analytical Reagents	Analytical Service
Measured Analytes	Cannabinoids	carboxy-THC
Test Medium	Urine	Hair
Cut-off levels	20, 50 and 100 ng carboxy-THC/mL	1 pg/10 mg hair
Test System(s)	Competitive Enzyme Immunoassay	Competitive Radioimmunoassay in combination with Gas Chromatography Mass Spectrometry Mass Spectrometry
Materials	Polyclonal primary antibody; enzyme-labeled carboxy-THC; optical assay of enzyme substrate	Polyclonal primary antibody; isotopically labeled carboxy-THC; double antibody precipitation and Dual derivatization Negative Chemical Ionization
Indications for Use	Identify Marijuana Use	Identify Marijuana Use
Target Population	Medical	Medical
Report Quantitation	No	Yes

VI. SUMMARY OF RADIO-IMMUNOASSAY (RIA) STUDIES

1. Removal of "Universal Cross-Reactor", Matrix Effects and LOD

One or several cross-reactors occurring universally in hair samples are removed from hair digests with a US Patented Procedure in which a DEAE Sephadex anion exchange resin is mixed with the digested hair sample. After mixing, the Sephadex-digest mixture is centrifuged and the supernatant assayed by the RIA procedure. Without the resin, the 1 S.D. range of the %B/Bo of pre-selected 100 negative hair samples was 53.2-77.2. After treatment for removal of the cross reactor the mean %B/Bo of the same negatives was 96.9, with an S.D. of 3.75.

Once the cross-reactor(s) has(have) been removed by the resin treatment, the remaining variability of the pre-selected negatives may be considered to be matrix effects. The magnitude of the matrix effects determines the Limit of detection (LOD) for the assay. At the level of 10 pg-equivalents carboxy-THC/10 mg hair (2.5 pg/assay tube), the lowest standard for which inter-assay precision data was generated, the mean pg-equivalents/tube was 2.5 (10 pg-equivalents/10 mg hair), with a central 95% confidence range of 2.0 – 2.9 (8.0 – 11.6 pg equivalents/10 mg hair).

2. Matrix Effects at the Cutoff

The resin treatment removes universal cross-reactor(s)and the cannabinoids that are normally used for the detection of marijuana use. Surrogate compound(s) not removed by the resin have been demonstrated to be useful in substantially reducing the number of samples that need to be tested with GC/MS/MS to determine marijuana use. The cutoff standard for the RIA assay is 5 pg carboxy-THC added after resin treatment (equivalent to 20 pg/10 mg hair).

Variable matrix effects of different hair samples were also measured at the cutoff. The same pre-selected 100 negative samples analyzed for the matrix study at zero concentration were spiked after the resin treatment at the 5 pg-equivalent carboxy-THC cutoff. A second set of 100 negatives was spiked with DEAE Sephadex treated hair digest (Marijuana Use Surrogate Marker) derived from previously tested positive hair in an amount that gave a %B/Bo depression similar to the cutoff standard.

Matrix Effects of 100 Different hair Samples at the Cutoff Concentration

	Sample Size (N)	Mean %B/Bo	S.D. %B/Bo	C.V. %
5 pg carboxy-THC	100	68.0	2.84	4.18
DEAE Sephadex treated Digest from Positive Hair	100	64.3	3.34	5.19

3. Intra-assay Precision for Marijuana Use Surrogate Marker.

The intra-assay analytical precision around the cutoff was determined by spiking, before digestion, RIA negative hair (%B/Bo near 100) with amounts of previously prepared surrogate marker(s) in amounts calculated to give %B/Bo depressions similar to + 25%, + 50%, -25%, -50% and 100% of the cutoff concentration determined by spiking resin supernatant with 5 pg carboxy-THC.

Comment: Matrix Effects of 100 Different Hair Samples at the Cut-Off Concentration

Intra-Assay Precision of Assay for Surrogate Marker(s)

pg Equivalents Carboxy-THC	Mean	Central 90% Confidence Interval
2.5	2.6	2.3 - 3.0
3.75	3.6	3.3 - 4.0
5.0	4.9	4.1 - 5.7
6.25	6.2	5.7 - 6.8
7.5	7.5	6.7 - 8.4

4. Inter Assay Precision for Marijuana Use Surrogate Marker(s).
Inter-assay precision around the Carboxy-THC cut-off was determined among 20 different assays performed (2 per day) for 10 days. The assays were performed by spiking, before digestion, RIA negative hair (%B/Bo near 100) with amounts of previously prepared cannabinoids in amounts calculated to give %B/Bo depressions similar to + 25%, + 50%, -25%, -50% and 100% of the cutoff concentration determined by spiking resin supernatant with 5 pg carboxy-THC.

Inter-Assay Precision of Assay for Surrogate Marker(s)

pg Equivalents Carboxy-THC	Mean	Central 90% Confidence Interval
2.5	2.5	2.0 - 2.9
3.75	3.7	3.3 - 4.3
5.0	5.2	4.6 - 5.9
6.25	6.2	5.7 - 7.1
7.5	7.6	6.6 - 9.1

5. Evaluation of the Cross Reactivity of the Antibody in the Assay
The cross-reactivities of several key cannabinoids were evaluated. The reactivity of these compounds individually with the antibody is not by itself relevant to the assay; rather it is the combination of their reactivities and the amounts remaining in the digest after resin treatment that determines any role of these compounds in the detection of marijuana use by the assay. The relative reactivities of various cannabinoids, and the remaining reactivity at the cut-off after resin treatment are listed below.

Amount of Compound in Digest that Produces a % B/Bo Response Equivalent to a 5 pg carboxy-THC Spiked Standard in Assay Tube		
	With No Resin	**After Resin Treatment of Digest**
l -11-nor-9-Carboxy-Δ^9-THC	5	750
d,l -11-nor-9-Carboxy-Δ^9-THC	14	1000
d,l -11-Hydroxy-Δ^9-THC	6.5	900
l -11-Hydroxy-Δ^9-THC	3.5	600
-Δ^8-THC	7.5	>2000
l -Δ^9-THC	25	>2000
Cannabidiol	>50	>3000
Cannabinol	8.5	>3000
l -9-Carboxy-11-nor-Δ^9-THC glucuronide	3	900
11-nor-9-Carboxy-Δ^8-THC	3.5	510

When the following compounds were analyzed in the Marijuana Assay at the 10,000 ng/10 mg hair level, no cross- reactivity was observed: oxazepam, cocaine, benzoylecgonine, cocaethylene, phencyclidine, chlorpromazine, diazepam, flurazepam, glutethimide, methaqualone, trimipramine, doxepin, imipramine, desipramine, protryptyline, pheniramine, doxylamine, orphenadrine, methapyraline, diphenopyraline, promethazine, amobarbital, butabarbital, secobarbital, medazepam, oxazepam, lorazepam, diazepam, temazepam, bromazepam, ethosuximide, methsuximide, normethsuximide, mephenytoin, PEMA, MPEMA.

6. Stability of the Radioactive Tracer and Antibody Solutions

The stabilities of the prepared first and second antibody reagents and tracer were tested by comparing various parameters at the time of preparation and after one month of the reagents being in use. The Bo/T x 100, the NSB (as B/Bo x 100) and the B/Bo x 100 depressions of the standards over the range of the curve were compared. The responses did not change over the one-month use and storage conditions.

7. Analytical Performance of the RIA Assay

Analytical performance of the device was calculated using head hair samples that were previously analyzed by hair RIA and when positive confirmed by GC/MS/MS. The samples were pre-selected according to the following categories: 106 negative samples with $\%B/B_0$ near 100, 92 negative samples with $\%B/B_0$ between the cutoff and 85, 120 positive samples with $\%B/B_0$ values between 60 and the cutoff, and 120 positive samples with $\%B/B_0$ less than 60. Confirmation was performed in the negative samples directly on the quick digest.

Analytical Performance of Marijuana RIA

RIA	GC/MS/MS Positive	GC/MS/MS Negative
Positive	93	147
Negative	2	196

VII. Summary of Gas Chromatography Mass Spectrometry Mass Spectrometry Studies

1. Significance of Confirmation using carboxy-THC

The presence of carboxy-THC other than as a human metabolite of marijuana has not been reported. However, presumptive positive hair samples are re-weighed, washed to eliminate any possibility of external contamination and analyzed by mass spectrometry. Digestion of negative hair samples spiked with 10 ng THC/10 mg hair have been shown not to generate carboxy-THC in the digestion, above the level of detection of GC/MS/MS .

2. Sample Preparation

Screen positive samples from the device are confirmed by first weighing out a new portion of the sample (approximately 10-16 mg). The samples are washed with shaking at 120 cycles/minute for 15 minutes at 37C with 2 mL dry ispropanol and then three times for 30 minutes in 2 ml phosphate buffer (0.01M, pH 6.0) containing 0.1% albumin. The hair is then spiked with 2.5 pg d_3-carboxy-THC/10 mg hair and digested for 1 hour at 70C using methanolic Potassium Hydroxide. Digested samples are then extracted from the digest using solid phase extraction (SPE) followed by derivatization with heptafluorobutyric anhydride (HFBA), heptafluoro-1-butanol (HFBO) and pentafluoro-1-propanol (PFPO). Samples are analyzed by GC/MS/MS for carboxy-THC monitoring two product ion ratios (*m/z* 524/527 and *m/z* 474/477) using a triple stage quadrupole instrument operating in the negative chemical ionization mode.

3. Linearity

The linear range of the method was determined by analyzing negative hair specimens spiked with 11 -nor-9-carboxy-Δ^9-tetrahydrocannabinol (THCA) at the following concentrations followed by a negative; 0 pg/10 mg hair, 0.2 pg/10 mg hair, 0.4 pg/10 mg hair, 0.5 pg/10 mg hair, 1.0 pg/10 mg hair, 2.5 pg/10 mg hair, 10.0 pg/10 mg hair, 25.0 pg/10 mg hair and 50.0 pg/10 mg hair. Each standard in the linear range quantitated within 25% of the target, had an acceptable symmetrical peak shape at an acceptable retention

time (within 2% of standards). The linear range was determined to be from 0.2 pg/10 mg hair to 50.0 pg/10 mg hair for 11-Nor-9-carboxy-Δ^9-tetrahydrocannabinol.

4. Sensitivity

The sensitivity of the method is determined using the linearity standards. The Limit of Detection (LOD) and the Limit of Quantitation (LOQ) for this method have been determined to be 0.2 pg/10 mg hair for 11-Nor-9carboxy-Δ^9-Tetrahydrocannabinol.

5. Elimination of Carryover

Elimination of carryover has been determined using the linearity standards followed by a negative sample containing the internal standard. Each negative following the linearity standard was examined for evidence of carryover. No carryover greater than the LOD was evident after any linearity standard up to and including the 50.0 pg/10 mg hair linearity standard.

6. Intra Assay Precision

Ten standards containing 0.5 pg 11-Nor-9-carboxy-Δ^9-Tetrahydrocannabinol/10 mg hair were assayed in one batch and had the following statistical result:
(*m/z* 474/477) Average = 0.50 pg, SD = 0.03, %CV = 5.4
(*m/z* 524/527) Average = 0.50 pg, SD = 0.04, %CV = 7.6

Nine standards containing 1.0 pg 11-Nor-9-carboxy-Δ^9-Tetrahydrocannabinol/l0 mg hair were assayed and had the following statistical result:
(*m/z* 474/477) Average = 1.05 pg, SD = 0.05, %CV = 5.0
(*m/z* 524/527) Average = 1.02 pg, SD = 0.05, %CV = 4.7

7. Inter Assay Precision

Controls at 0.8 pg/10 mg hair and 2.5 pg/10 mg hair were assayed 32 times over 31 days.
For 0.8 pg/10 mg hair a mean value of 0.73 pg/10 mg hair was obtained with an approximate central 94% confidence range of 0.62 to 0.97 pg/10 mg.
For 2.5 pg/10 mg hair a mean value of 2.24 pg/10 mg was obtained with an approximated central 94% confidence range of 1.9 to 2.8 pg/10 mg.

8. Precision of Deuterated Internal Standard Signal

a. Intra-Batch

The variation permitted in the signal strength (peak area) of the ions belonging to the spiked deuterated internal standard, namely *m/z* 477 and *m/z* 527, of any sample must equal or exceed 50% of the mean signal strength for the standards and controls. Otherwise the sample injection is repeated or re-analyzed. The %CV of intra-batch variations for five lots used in the validation of the method and the clinical studies are given in the table below.

Batch	*N*	*Mean Count m/z 477*	*SD*	*%CV*	*Mean Count m/z 527*	*SD*	*%CV*
1	*43*	*66100*	*10209*	*15.4*	*47096*	*5437*	*11.5*
2	*55*	*55142*	*13608*	*24.7*	*40516*	*9343*	*23.1*
3	*84*	*75506*	*16016*	*21.2*	*52300*	*10882*	*20.8*
4	*69*	*76640*	*5450*	*7.1*	*52668*	*3095*	*5.9*
5	*55*	*81796*	*9718*	*11.9*	*55680*	*7025*	*12.6*
6	*33*	*72958*	*8230*	*11.3*	*49719*	*5334*	*10.7*
7	*77*	*57979*	*11749*	*20.3*	*40195*	*7691*	*19.1*

b. Inter-Batch

The %CV of inter-batch variations of the ions belonging to the deuterated internal standard, namely *m/z* 477 and *m/z* 527, have been calculated to be 16.0 and 14.8 respectively.

9. Accuracy
The accuracy of the method is determined using the linearity standards. Each linearity standard quantitated within ± 25% of its target value. The method is accurate within its linear range of 0.2 pg/10 mg hair to 50.0 pg/10 mg hair for 11-Nor-9-carboxy-Δ^9-Tetrahydrocannabinol.

10. Negative Study - RIA Negative Specimens
Batches containing RIA marijuana negative specimens (n=246) were analyzed by the method. All specimen results were negative. Two hundred and forty six specimens quantitated below the level of detection. Two specimens quantitated at 0.6 pg and 0.7 pg/10 mg.

11. Reporting Positive Results
The following criteria must be met before reporting a positive result:
a. Batch controls at 2.5 pg and 0.8 pg must quantitate within + or - 25% of the target.
b. Batch negative open controls must be negative and below LOD.
c. Quantitation ions must exceed a S/N of 10 or greater.
d. Retention time of sample eluate must be within 2% of the mean of the standards.
e. Peak shapes should be as close to Gaussian with no more than 50% tailing.
f. Quantitative results from both ion pairs must be within + or - 25% of the average of the two results.
g. Both quantitative values must be equal to or above 1 pg/10 mg hair.
h. The final reporting value is that derived from the *m/z* 524/527 ion pair.
i. Peak area for the internal standard must be ∃50% of the mean of the combined standard and controls.

VIII. PERCENTAGE AGREEMENT STUDIES

1. Positive & Negative Percent Agreement
Studies on drug using subjects were conducted at four rehabilitation clinics. A total of 75 subjects who tested positive by EMIT for carboxy-THC, on at least one of two urine samples, contributed hair samples. Five of those subjects were excluded from further study when the urine samples did not confirm for the presence of carboxy-THC by mass spectrometry. Fourteen subjects were excluded due to protocol violations on the timing of collection of the samples, and five due to insufficient sample. Of the remaining 51 samples, 39 head hair samples screened positive by RIA for Marijuana use. Thirty eight of the thirty nine screen positive samples confirmed positive by GC/MS/MS.

The 51 subjects included 19 females and 32 males; 19 Hispanics, 9 African Americans, and 23 Caucasians. The ages of the subjects ranged from 20 to 70 years. There were 18 black hair samples, 25 brown hair samples, 7 salt pepper samples and one red hair.

Negative percent agreement was measured by the analysis of hair and urine from 73 volunteers who provided 2 urine samples per week for 5 weeks. The urine samples were screened and confirmed at the limit of detection for the NIDA-5 drug panel. All urines were negative for carboxy-THC in the screen and by confirmation. Hair was collected 6 weeks following the first urine collection. Sixty nine samples were negative in the RIA Assay and by mass spectrometry, four samples were dropped due to the lack of sample for confirmation. The mean B/Bo result of the samples was 100.0, with a range of 74.7 to 110.6. These negative subjects comprised 40 females, 29 males: 6 African-American, 21 Caucasians, 29 Asians, 13 Hispanics: 47 black hair color, 16 brown hair color, 2 blond and 4 salt and pepper.

RIA SCREENING ONLY

Hair Analysis	Urine Analysis Positive	Urine Analysis Negative
Positive	39	0
Negative	12	69

Positive Percent Agreement = 39/51= 76.5%
[95% confidence intervals: 62.5% to 87.2%]

Negative Percent Agreement = 100%
95% confidence intervals: 94.8% to 100%]

RIA SCREENING PLUS MS CONFIRMATION

Hair Analysis	Urine Analysis Positive	Urine Analysis Negative
Positive	38	0
Negative	13	69

Positive Percent Agreement = 38/54 = 74.5%
95% confidence intervals: 60.4% to 85.7%]

Negative Percent Agreement = 100%
95% confidence intervals: 94.8% to 100%]

2. Body Hair

Seventeen of the drug-using subjects submitted 47 body hair samples. Twelve of those subjects (33 samples) were excluded for protocol violations, one subject was excluded due to insufficient body hair samples and one sample from anther subject was excluded due to insufficient sample for confirmation. A total of eleven samples from 4 subjects were analyzed. Twenty one of the individual negative subjects also donated a total of 32 body hair samples at the time of the head hair collection. Eighteen of those samples were of insufficient size to perform confirmation leaving a total of 4 chest hair samples, 5 leg hair samples, and 5 underarm hair samples . Two samples of the eighteen not process through confirmation tested positive by RIA. Additional samples from the same employees were taken six months later to obtain a total of 10 chest hair samples, 22 leg hair samples and 16 underarm hair samples.

a. Chest Hair Percent Agreement

Chest Hair Analysis RIA + GC/MS/MS	Urine Analysis EMIT + GC/MS Positive	Urine Analysis EMIT + GC/MS Negative
Positive	2	0
Negative	1	10

Positive Percent Agreement for chest hair analysis (RIA + GC/MS/MS) relative to urine = 2/3 = 66%
[95% confidence intervals: 9.4% to 99.2%]

Positive Percent Agreement for chest hair analysis relative to head hair analysis = 3/3 = 100%
[95% confidence intervals: 29.2% to 100%]

Negative Percent Agreement = 10/10 = 100%
[95% confidence intervals: 69.2% to 100%]

b. Underarm Hair Percent Agreement

Underarm Hair Analysis RIA + GC/MS/MS	Urine Analysis EMIT + GC/MS Positive	Urine Analysis EMIT + GC/MS Negative
Positive	3	0
Negative	1	16

Positive Percent Agreement for underarm hair analysis (RIA + GC/MS/MS) relative to urine = 3/4=75%
[95% confidence intervals: 19.4% to 99.4%]

Positive Percent Agreement for underarm hair analysis relative to head hair analysis = 4/4 = 100%
[95% confidence intervals: 39.8% to 100%]

Negative Percent Agreement = 16/16 = 100%
[95% confidence intervals: 79.4% to 100%]

c. Leg Hair Percent Agreement

Leg Hair Analysis RIA + GC/MS/MS	Urine Analysis EMIT + GC/MS Positive	Urine Analysis EMIT + GC/MS Negative
Positive	4	0
Negative	0	22

Positive Percent Agreement for leg hair analysis (RIA + GC/MS/MS) relative to urine = 4/4 = 100%
[95% confidence intervals: 39.8% to 100%]

Positive Percent Agreement for leg hair analysis relative to head hair analysis = 3/4 = 100%
[95% confidence intervals: 19.4% to 99.4%]

Negative Percent Agreement = 22/22 = 100%
[95% confidence intervals: 84.6% to 100%]

<end>
Revised May 01, 2002/TCairns

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Thomas Cairns, PhD, DSc
Senior Scientist
Psychemedics Corporation
5832 Uplander Way
Culver City, CA 90230

MAY 3 2002

Re: k011426
Trade/Device Name: Psychemedics Marijuana Screening and Confirmatory Test System
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: LAT
Dated: March 8, 2002
Received: March 11, 2002

Dear Dr. Cairns:

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 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); 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.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(K) Number: (K011426)

Device Name: **Psychemedics Marijuana Screening and Confirmatory Test System**

Indications for Use:
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 C-THC/10 mg hair for the purposes 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 non-professionals. Clinical consideration and professional judgement should be applied to any drug of abuse test result.

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

Jean Cooper

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Clinical Laboratory Devices
510(k) Number K011426

Prescription Use ✓ **OR** **Over-the-Counter Use**
(Per 21 CFR 801.109)