April 18, 2022

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

Re: K212952
Trade/Device Name: Psychemedics Homogeneous Enzyme Immunoassay (HEIA) for Phencyclidine in Hair
Regulatory Class: Unclassified, 510(k) required
Product Code: LCM
Dated: February 23, 2022
Received: February 24, 2022

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)*
k212952

Device Name
Psychemedics Homogeneous Enzyme Immunoassay (HEIA) for Phencyclidine in Hair

Indications for Use *(Describe)*
The Psychemedics homogeneous enzyme immunoassay (HEIA) for phencyclidine in hair is an enzyme immunoassay system for the preliminary qualitative detection of phencyclidine in human head and body hair using a phencyclidine calibrator at 3 ng phencyclidine/10 mg hair for the purpose of identifying phencyclidine use.

This is an in vitro diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone. The Psychemedics phencyclidine 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. Gas Chromatography/Mass Spectrometry (GC/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.**

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**007_Phencyclidine Homogeneous Enzyme Immunoassay in Hair 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: k212952


**Submitted By:** Psychemedics Corporation

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**Submission Contact:** Neil Stowe


**Date Prepared:** 4-12-2022

**Device Trade Name:** Psychemedics Homogeneous Enzyme Immunoassay (HEIA) for Phencyclidine in Hair

**Predicate Device:** Psychemedics Microplate EIA for Phencyclidine in Hair, k111928

**Product Code:** LCM (Phencyclidine Test System),

**Device/Classification Name:** Enzyme Immunoassay Phencyclidine

**Intended Use:** The Psychemedics homogeneous enzyme immunoassay (HEIA) for phencyclidine in hair is an enzyme immunoassay system for the preliminary qualitative detection of phencyclidine in human head and body hair using a phencyclidine calibrator at 3 ng phencyclidine/10 mg hair for the purpose of identifying phencyclidine use.

This is an *in vitro* diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone. The Psychemedics phencyclidine 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. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method.

**Device Description:** The test consists of two parts; a pre-analytical hair treatment procedure (to extract phencyclidine from the solid hair matrix to a measurable liquid matrix) and the screening assay, the Psychemedics Phencyclidine Homogeneous Enzyme Immunoassay. 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 Phencyclidine HEIA consists of reagents R1 (anti-phencyclidine monoclonal antibody with substrate) and R2 (phencyclidine 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 phencyclidine in hair samples stored at room temperature has been shown for at least 8 months. Phencyclidine in samples shipped coast-to-coast twice was stable.

**Materials Required:** Hair sample collection kit, Homogeneous Enzyme Immunoassay for Phencyclidine, automated clinical chemistry analyzer, GC/MS for confirmation.

**Comparison with Predicate Devices:**

| Item | Proposed Device | Psychemedics Phencyclidine Assay, k111928 |
|---|---|---|
| **Indications/Intended Use** | The Psychemedics homogeneous enzyme immunoassay (HEIA) for phencyclidine in hair is an enzyme immunoassay system for the preliminary qualitative detection of phencyclidine in human head and body hair using a phencyclidine calibrator of 3 ng phencyclidine/10 mg hair for the purpose of identifying phencyclidine use. This is an *in vitro* diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone.<br>The Psychemedics Phencyclidine 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. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. | The Psychemedics Microplate EIA for Phencyclidine is an enzyme immunoassay (EIA) for the preliminary qualitative detection of phencyclidine in human head and body hair samples using a phencyclidine calibrator at 3 ng/10 mg hair cutoff for the purpose of identifying phencyclidine use. This is an in vitro diagnostic device intended for exclusively for Psychemedics use only and is not for sale to anyone.<br>The Psychemedics EIA phencyclidine Assay provides only a preliminary analytical test result. To obtain a quantitative analytical result or to confirm positive results, a more specific alternate chemical method (e.g. GC/MS) must be used. Clinical consideration and professional judgement should be applied to the interpretation of any drug-of-abuse test result. |
| **Product Code** | LCM | LCM |
| **Measurand** | Phencyclidine | Phencyclidine |
| **Test System** | Psychemedics Homogeneous Enzyme Immunoassay for Phencyclidine in Hair | Psychemedics Microplate EIA for Phencyclidine in Hair |
| **Sample Matrix** | Human Hair | Human Hair |
| **Method of Measurement** | Automated Clinical Chemistry Analyzer at 340 nm | Microplate Reader at 450 nm |
| **Type of Test** | Enzyme Immunoassay | Enzyme Immunoassay |
| **Extraction Method** | Acidic aqueous buffer | Patented Digestion Method |
| **Confirmation Method** | GC/MS | GC/MS |

**Performance Testing Summary:** Precision studies were performed by spiking negative hair with previously GC/MS validated calibrator and control solutions to achieve concentrations of negative, the cutoff calibrator of 3 ng phencyclidine/10 mg hair and +/- 75%, +/- 50% and +/-25% of the cutoff calibrator.

| Phencyclidine Intra-Assay and Inter-Assay Precision Summary, 3 ng Phencyclidine/10 mg Hair Calibrator | | | | | | |
|---|---|---|---|---|---|---|
| **Summary Intra-Assay Precision** | | | | **Summary Inter-Assay Precision** | | |
| Level | NEG | POS | | Level | NEG | POS |
| -100% | 8 | 0 | | -100% | 80 | 0 |
| -75% | 8 | 0 | | -75% | 80 | 0 |
| -50% | 8 | 0 | | -50% | 80 | 0 |
| -25% | 8 | 0 | | -25% | 80 | 0 |
| +25% | 0 | 8 | | +25% | 0 | 80 |
| +50 | 0 | 8 | | +50 | 0 | 80 |
| +75% | 0 | 8 | | +75% | 0 | 80 |
| +100% | 0 | 8 | | +100% | 0 | 80 |

**Cross Reactivity Summary:** The cross reactivity of the following metabolites and phencyclidine structural analogs was evaluated by determining the minimum concentration that would result approximately equivalent to the 3.0 ng phencyclidine/10 mg hair cutoff.

| Cross Reactivities, Phencyclidine 3 ng/10 mg Calibrator, Structurally Related Compounds and Metabolites | | |
|---|---|---|
| Compound | % Cross Reactivity | Concentration Equivalent to 3.0 ng Phencyclidine/10 mg Hair |
| Venlafaxine | 100 | 3 |
| Rolicyclidine HCl | 37.5 | 8 |
| 3-Methoxy-(Aryl Ring) PCP | 30 | 10 |
| 4-Hydroxy (Cyclohexyl Ring) PCP | 12 | 25 |
| 1-(1-Phenylcyclohexyl)-4-hydroxypiperidine | 6 | 50 |
| 1-(1-Phenylcyclohexyl) Morpholine (PCM) | 6 | 50 |
| Metaphit | 4 | 75 |
| Atropine | 3 | 100 |

The following compounds were shown to have no cross reactivity in the phencyclidine assay using the 3 ng phencyclidine/10 mg hair calibrator.

Anhydroecgonine Methyl Ester, Bupropion, Cotinine, Cannabinol, Chlorpheniramine Maleate, O-Desmethylvenlafaxine, Desipramine, Doxylamine Succinate, 1S, 2R-(+)-Ephedrine, Naproxen, Nicotine, Nortriptyline, H-Propoxyphen, R, R-(-)-Pseudoephedrine, Thioridazine, cis-Tramadol, (±)-11-nor-9-Carboxy-Δ9-THC, Pentazocine, Amoxicillin, Propranolol, Promethazine, Phenmetrazine, Phendimetrazine, Benzocaine, Ecgonine, Dextromethorphan, Amitriptyline, R-(-)-Phenylephrine, Glutethimide, Meprobamate, Lidocaine, Carbamazepine, Diazepam, Nordiazepam, AM-2201, JWH-019, JWH-081, JHW-122, Acetaminophen, Caffeine, Dyphylline, Methaqualone, Theophylline, CP47.497, CP47.497 C8 Homologue, HU-211, JWH-200, JWH-250, Ibuprofen, Naproxen, Ethosuximide, (±)-Epinephrine, Norepinephrine, Barbital, Metanephrine, Normetanephrine, Methocarbamol, Alprazolam, Cimoticline, Citalopram, Clopidogrel Bisulfate, Fluconazole, Hydrochloro-thiazide, Lamotrigine, L-Thyroxine, Methyl Phendiate, Omeprazole, Amlodipine Besylate, Atorvastatin, Azithromycin, Bupivacaine, Cetirizine, Dimenhydrinate,

Lisinopril, Methsuximide, Phensuximide, N-Normethyl Suximide, Butabarbital, Amobarbital, Secobarbital, Hexobarbital, Phenobarbital, Mephyton, Ethotoin, Mephobarbital, PEMA, 10,11-Dihydro-carbamazepine, Medazepam, Chlorpramazine, Flurazepam, Lorazepam, Temazepam, Bromazepam, Primidone, 5,5-Diphenyl Hydantoin, Triamterene, Nordoxepin, Oxazepam, Levitriacetam, Metformin, Phenytoin, R-Phenyl-ephrine, Sertraline, Topiramate, Zolpidem Tartrate, Vanilmandelic Acid, 5-Hydroxy Indole-3-Acetic Acid, Homovanilic Acid

**Interference:**

The compounds atropine, chlorpheniramine maleate and venlafaxine were interferences in the immunoassay when tested at 100 ng interferent per 10 mg hair.

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

Anhydroecgonine Methyl Ester, Bupropion, Cotinine, Cannabinol, O-Desmethylvenlafaxine, Desipramine, Doxylamine Succinate, 1S, 2R-(+)-Ephedrine, Naproxen, Nicotine, Nortriptyline, H-Propoxyphen, R, R-(-)-Pseudoephedrine, Thioridazine, cis-Tramadol, (±)-11-nor-9-Carboxy-Δ9-THC, Pentazocine, Amoxicillin, Propranolol, Promethazine, Phenmetrazine, Phendimetrazine, Benzocaine, Ecgonine, Dextromethorphan, Amitriptyline, R-(-)-Phenylephrine, Glutethimide, Meprobamate, Lidocaine, Carbamazepine, Diazepam, Nordiazepam, AM-2201, JWH-019, JWH-081, JHW-122, Acetaminophen, Caffeine, Dyphylline, Methaqualone, Theophylline, CP47.497, CP47.497 C8 Homologue, HU-211, JWH-200, JWH-250, Ibuprofen, Naproxen, Ethosuximide, (±)-Epinephrine, Norepinephrine, Barbital, Metanephrine, Normetanephrine, Methocarbamol, Alprazolam, Cimoticline, Citalopram, Clopidogrel Bisulfate, Fluconazole, Hydrochloro-thiazide, Lamotrigine, L-Thyroxine, Methyl Phendiate, Omeprazole, Amlodipine Besylate, Atorvastatin, Azithromycin, Bupivacaine, Cetirizine, Dimenhydrinate, Lisinopril, Methsuximide, Phensuximide, N-Normethyl Suximide, Butabarbital, Amobarbital, Secobarbital, Hexobarbital, Phenobarbital, Mephyton, Ethotoin, Mephobarbital, PEMA, 10,11-Dihydro-carbamazepine, Medazepam, Chlorpramazine, Flurazepam, Lorazepam, Temazepam, Bromazepam, Primidone, 5,5-Diphenyl Hydantoin, Triamterene, Nordoxepin, Oxazepam, Levitriacetam, Metformin, Phenytoin, R-Phenyl-ephrine, Sertraline, Topiramate, Zolpidem Tartrate, Vanilmandelic Acid, 5-Hydroxy Indole-3-Acetic Acid, Homovanilic Acid

**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 GC/MS.

**Sample Shipping Stability During Storage:** 7 phencyclidine positive samples remained positive after approximately 8 months in storage and after shipping twice coast-to-coast.

**Recovery:** The hair sample preparation for the screening HEIA is a phosphate buffer extraction procedure. Recovery of phencyclidine in the method was shown on average to be approximately 86% complete after extraction for 3 hours.

**Cosmetic Treatments:** 5 phencyclidine-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 5 samples treated with a type of cosmetic treatment, all samples remained negative after the treatments.

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

**Comparison Studies:** *Phencyclidine, 3 ng phencyclidine/10 mg hair calibrator*

Samples positive or negative for phencyclidine were identified using the Psychemedics phencyclidine microplate assay (k111928), and then tested with the test device, the Psychemedics HEIA for phencyclidine in hair. The test device (assay) has been validated at the 3 ng phencyclidine/10 mg hair cutoff using 84 individual hair samples collected anonymously from a workplace setting. 40 negative samples and 44 positive samples were identified by the test device.

The stored hair samples were then tested using Psychemedics' GC/MS confirmatory assay, to compare the Psychemedics HEIA results with the GC/MS results. The studies comparing the HEIA with GC/MS documented the source of hair (head or body) and other demographics as available. The comparison of the Psychemedics Phencyclidine HEIA at the 3 ng/10 mg hair calibrator with GC/MS is shown in the following table.

| Phencyclidine 3 ng/10 mg hair Calibrator Comparison Study | | | | |
|---|---|---|---|---|
| HEIA Result | Unwashed GC/MS Result, ng Phencyclidine/10 mg hair (% of cutoff calibrator) | | | |
| | < 1.5 (< 50% below cutoff) | 1.50 – 2.99 (≥ 50% below cutoff to cutoff) | 3.0 – 4.50 (cutoff to ≥ 50% above cutoff) | > 4.50 (> 50% above cutoff) |
| Positive | 0 | 0 | 4 | 40 |
| Negative | 36 | 4 | 0 | 0 |

| Phencyclidine 3 ng/10 mg hair Calibrator Comparison Study | | | | |
|---|---|---|---|---|
| HEIA Result | Washed GC/MS Result, ng Phencyclidine/10 mg hair (% of cutoff calibrator) | | | |
| | < 1.5 (< 50% below cutoff) | 1.50 – 2.99 (≥ 50% below cutoff to cutoff) | 3.0 – 4.50 (cutoff to ≥ 50% above cutoff) | > 4.50 (> 50% above cutoff) |
| Positive | 0 | 2 | 7 | 35 |
| Negative | 36 | 4 | 0 | 0 |

Phencyclidine Discordant Results at the 3 ng phencyclidine/10 mg hair calibrator: Positive HEIA/Negative GC/MS

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

| Sample | HEIA Result | Unwashed GC/MS Result (ng Phencyclidine/10 mg hair) | Washed GC/MS Result (ng Phencyclidine/10 mg hair) | Comment |
|---|---|---|---|---|
| 1 | POS | 4.85 | 1.73 | Sample 1 confirmed ≥ 3.0 ng phencyclidine/10 mg unwashed, < 3.0 ng phencyclidine/10 mg after extended washing. |
| 2 | POS | 3.65 | 2.47 | Sample 2 confirmed ≥ 3.0 ng phencyclidine/10 mg unwashed, < 3.0 ng phencyclidine/10 mg after extended washing. |

**Conclusion:**

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