April 20, 2021

Elina Arroyo
Manager Regulatory Affairs
Immunalysis Corporation
829 Towne Center Drive
Pomona, CA 91767

Re: k203489
Trade/Device Name: SEFRIA PCP Oral Fluid Enzyme Immunoassay
Regulatory Class: unclassified, 510(k) required
Product Code: LCM
Dated: November 24, 2020
Received: November 27, 2020

Dear Elina Arroyo:

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,

Kellie B. Kelm, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k203489

Device Name
SEFRIA™ PCP Oral Fluid Enzyme Immunoassay

Indications for Use *(Describe)*
For In Vitro Diagnostic Use.

The Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay is an enzyme immunoassay with a cutoff of 10 ng/mL in neat oral fluid collected by Quantisal or Quantisal II Oral Fluid Collection Device. The assay is intended for the qualitative and semi-quantitative analysis of PCP in human oral fluid with clinical analyzers. This assay is calibrated against PCP.

The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Gas Chromatography/Mass Spectrometry (GC-MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

The Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/ Mass Spectrometry (GC-MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are used.

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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510(K) SUMMARY

A. GENERAL INFORMATION

Applicant Name: Immunalysis Corporation
829 Towne Center Drive
Pomona, CA 91767
Establishment # 2020952

Company Contact: Wenying (Jessica) Zhu
Manager, Regulatory Affairs
Phone: (909) 451-6697

Date Prepared: November 24, 2020

B. DEVICE IDENTIFICATION

Trade or Proprietary Names: SEFRIA PCP Oral Fluid Enzyme Immunoassay

Common Name: PCP Oral Fluid Enzyme Immunoassay

C. REGULATORY INFORMATION

Device Classification Name: Enzyme Immunoassay, Phencyclidine

Product Codes: LCM

Regulatory Class: Unclassified

Classification Regulation: Unclassified

Panel: Toxicology (91)

Predicate Device: Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay [K181135]

D. DEVICE DESCRIPTION

The Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay is an *in vitro* diagnostic test to detect the presence of PCP in human oral fluid samples collected by Quantisal or Quantisal II Oral Fluid Collection Device.

Phencyclidine (PCP) was first synthesized in 1926 and later tested after World War II as a surgical anesthetic. Because of its adverse side effects, such as hallucinations, mania, delirium, and disorientation, it was shelved until the 1950s. The drug is easily synthesized by anyone with a basic knowledge of chemistry and has become one of the drugs most frequently used by drug abusers. It has a variety of street names, including "angel dust," "animal tranquilizer," "PCP," "peace pill," "crystal joints," and "peace weed," with the name often reflecting the form in which it is taken. It can be smoked, "snorted" through the nose, ingested, or taken intravenously. Phencyclidine has also been shown to cause schizophrenia-like changes in N-acetylaspartate and N-acetylaspartylglutamate in the rat brain, which are detectable both in living rats and upon necropsy examination of brain tissue. It also induces symptoms in humans that mimic schizophrenia. Behavioral effects can vary by dosage. Low doses produce numbness in the extremities and intoxication, characterized by staggering, unsteady gait, slurred speech, bloodshot eyes, and loss of balance. Moderate doses (5–10 mg intranasal, or 0.01–0.02 mg/kg intramuscular or intravenous) will produce analgesia and anesthesia. High doses may lead to convulsions. Users frequently do not know how much of the drug they are taking due to the tendency of the drug to be made illegally in uncontrolled conditions.

E. INTENDED USE

For *In Vitro* Diagnostic Use.

The Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay is a homogenous enzyme immunoassay with a cutoff of 10 ng/mL in neat oral fluid collected by Quantisal™ or Quantisal™ II Oral Fluid Collection Device. The assay is intended for the qualitative and semi-quantitative analysis of PCP in human oral fluid with clinical analyzers. This assay is calibrated against PCP.

The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Gas Chromatography/Mass Spectrometry (GC-MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

The Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/ Mass Spectrometry (GC-MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are used.

F. COMPARISON WITH PREDICATE

The selected predicate device is Immunalysis SEFRIA PCP Enzyme Immunoassay K181135.

Attribute	Candidate Device SEFRIA PCP Oral Fluid Enzyme Immunoassay	Predicate Device SEFRIA PCP Oral Fluid Enzyme Immunoassay [k181135]
Similarities		
Intended Use	Qualitative and semi-quantitative analysis of PCP in human oral fluid	Qualitative and semi-quantitative analysis of PCP in human oral fluid
Test Principle	Identical	Homogeneous enzyme immunoassay
Calibrated Against	Identical	PCP
Assay Materials	Identical	antibody reagent, drug conjugate reagent
Cutoff Level	Identical	10 ng/mL
User Environment	Identical	For use in laboratories
Sample Matrix	Identical	Human oral fluid
Reagent Storage	Identical	2-8°C until expiration date
Instrumentation	Identical	Automated clinical chemistry analyzer
Mass Spectrometry Confirmation	Identical	Required for preliminary positive analytical results
Differences		
Sample Collection Device	Oral fluid is collected with the Quantisal or Quantisal II Oral Fluid Collection Device. Samples are stored in plastic tubes containing preservative buffer with snap caps.	Oral fluid is collected with the Quantisal II Oral Fluid Collection Device. Samples are stored in plastic tubes containing preservative buffer with snap caps.

G. PERFORMANCE CHARACTERISTICS

The following laboratory performance studies were performed to determine substantial equivalence of the SEFRIA PCP Oral Fluid Enzyme Immunoassay to the predicate device. Assay performance was established using the Beckman Coulter AU480 chemistry analyzer.

1. Precision

Precision study was performed over 15 days, 2 runs per day with 2 collection devices per run (N=60), one replicate per collection device on 1 lot of reagent and 3 lots of Quantisal oral fluid collection devices. Drug free negative oral fluid was spiked to concentrations of assay cutoff and ±25%, ±50%, ±75%, ±100% of the cutoff and was collected using the collection devices. The spiked concentrations were confirmed by mass spectrometry (LC-MS/MS) before collection. The study established the repeatability of the testing system, including assay and oral fluid collection device. Test results in qualitative and semi-quantitative modes for a representative lot are presented in **Tables 1** and **2**.

Data for the candidate device used with Quantisal II device were reported in K181135.

Table 1. Precision – Qualitative

Concentration (ng/mL)	% of Cutoff	# of Determinations	Result
0	-100%	60	60 Negative
2.5	-75%	60	60 Negative
5	-50%	60	60 Negative
7.5	-25%	60	60 Negative
10	Cutoff	60	29 Neg/31 Pos
12.5	+25%	60	60 Positive
15	+50%	60	60 Positive
17.5	+75%	60	60 Positive
20	+100%	60	60 Positive

Table 2. Precision - Semi-Quantitative

Concentration (ng/mL)	% of Cutoff	# of Determinations	Mean Conc. (ng/mL)	Result
0	-100%	60	-0.2	60 Negative
2.5	-75%	60	2.3	60 Negative
5	-50%	60	4.9	60 Negative
7.5	-25%	60	7.3	60 Negative
10	Cutoff	60	10.1	30 Neg /30 Pos

12.5	25%	60	13.2	60 Positive
15	50%	60	15.9	60 Positive
17.5	75%	60	18.3	60 Positive
20	100%	60	21.7	60 Positive

2. Specificity and Cross-Reactivity

Data were reported in K181135.

3. Interference – Structurally Unrelated Compounds, Endogenous Compounds and Exogenous Compounds

Data were reported in K181135.

4. Interference – Orally Used Endogenous Compounds

Orally used exogenous compounds were evaluated in qualitative and semi-quantitative modes by spiking the potential interferent into drug free oral fluid containing PCP at ±25% of the cutoff. The drug free oral fluid samples were collected using Quantisal Oral Fluid Collection Device from volunteers after use of the substances. Orally used compounds tested are presented in **Table 3**. No interference was observed with any of the compounds at the concentrations tested.

Data for the candidate device used with Quantisal II device were reported in K181135.

Table 3. Non-interfering Orally Used Exogenous Products

Compound	Concentration Tested
Teeth Whitener	2 strips
Hydrogen Peroxide (3% OTC)	Neat (2 min mouth rinse)
Cigarette	1 cigarette
Hard Candy	1 piece
Chewing Gum	1 piece
Cough Syrup	2 Teaspoons

5. Interference – pH

Data were reported in K181135.

6. Linearity/Recovery

A linearity study in the semi-quantitative mode was conducted by spiking a drug free oral fluid pool

with a high concentration of PCP above the highest calibrator. Additional pools were made by serially diluting the high concentration specimen with drug free oral fluid to achieve concentrations ranging from 4 ng/mL to 44 ng/mL. The 0 ng/mL specimen was made from drug free oral fluid. Each pool was collected by Quantisal oral fluid collection device and tested in triplicate to calculate the mean concentration values that were used to calculate drug recovery. Linearity test results in semi-quantitative mode are presented in **Tables 4**. The study confirmed the linear range to be 4-40 ng/mL.

Data for the candidate device used with Quantisal II device were reported in K181135.

Table 4. Linearity/Recovery

Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
0	0.0	N/A
4	3.9	97.5
8	8.2	102.1
10	10.2	102.3
12	13.0	108.1
16	17.3	108.3
20	19.8	98.8
24	25.5	106.1
28	30.5	108.8
32	34.4	107.4
36	38.9	108.1
40	40.2	100.6
44	49.0	111.4

7. PCP Stability in Oral Fluid

Drug free negative oral fluid spiked with PCP at +50% of the 10 ng/mL cutoff were collected and stored in Quantisal and Quantisal II Oral Fluid Collection Devices at 2°C - 8°C, tested by LC-MS/MS at each time point and compared to the baseline concentration result. The test results indicate that oral fluid samples containing PCP are stable for up to 12 months stored in Quantisal or Quantisal II Oral Fluid Collection Device at 2°C - 8°C.

Data to support 10-day storage in Quantisal or Quantisal II Oral Fluid Collection Device at ambient temperature 8°C - 25°C were reported in K183048 and K200801.

8. Calibration Duration

Drug free negative oral fluid spiked with PCP at ±25% of the cutoff were tested in semi-quantitative at

time points up to 14 days. At the initial time point, a multi-points calibration curve was established in semi-quantitative mode. These calibrations were used through the duration of the study. The test results met acceptance criteria at each timepoint. The recommended frequency of calibration is 14 days.

Data for qualitative mode were reported in K181135.

9. Method Comparison

Eighty (80) deidentified, unaltered clinical oral fluid samples collected by Quantisal and Quantisal II Oral Fluid Collection Devices were obtained from drug treatment facilities, analyzed for PCP at assay cutoff with the SEFRIA PCP Oral Fluid Enzyme Immunoassay in both qualitative and semi-quantitative modes and compared to Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) results. The instruments used were the Beckman Coulter AU480 chemistry analyzer and an Agilent 6430 Liquid Chromatography/Tandem Mass Spectrometry. Method comparison test results in qualitative and semi-quantitative modes are presented from **Tables 5** to **7**.

Table 5. Method Comparison

Quantisal						
SEFRIA PCP Oral Fluid EIA Result		**LC-MS/MS PCP Neat Oral Fluid Concentration**				**Agreement (%)**
		< 5 ng/mL (less than -50% cutoff)	**5 – 9 ng/mL (between -50% cutoff and cutoff)**	**10 – 15 ng/mL (between cutoff and +50% cutoff)**	**> 15 ng/mL (greater than +50% cutoff)**	
Qual.	Positive	0	0	7	33	100% (40/40)
	Negative	36	4	0	0	100% (40/40)
Semi-Quant.	Positive	0	0	7	33	100% (40/40)
	Negative	36	4	0	0	100% (40/40)

Table 6. Method Comparison

Quantisal II A						
SEFRIA PCP Oral Fluid EIA Result		**LC-MS/MS PCP Neat Oral Fluid Concentration**				**Agreement (%)**
		< 5 ng/mL (less than -50% cutoff)	**5 – 9 ng/mL (between -50% cutoff and cutoff)**	**10 – 15 ng/mL (between cutoff and +50% cutoff)**	**> 15 ng/mL (greater than +50% cutoff)**	
Qual.	Positive	0	0	4	36	100% (40/40)
	Negative	36	4	0	0	100% (40/40)
Semi-Quant.	Positive	0	0	4	36	100% (40/40)
	Negative	36	4	0	0	100% (40/40)

Table 7. Method Comparison

Quantisal II B						
SEFRIA PCP Oral Fluid EIA Result		**LC-MS/MS PCP Neat Oral Fluid Concentration**				**Agreement (%)**
		< 5 ng/mL (less than -50% cutoff)	**5 – 9 ng/mL (between -50% cutoff and cutoff)**	**10 – 15 ng/mL (between cutoff and +50% cutoff)**	**> 15 ng/mL (greater than +50% cutoff)**	
Qual.	Positive	0	0	6	34	100% (40/40)
	Negative	36	4	0	0	100% (40/40)
Semi-Quant.	Positive	0	0	6	34	100% (40/40)
	Negative	36	4	0	0	100% (40/40)

H. CONCLUSION

The information provided in this pre-market notification demonstrates that the Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay is substantially equivalent to the legally marketed predicate device for its intended use.