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

April 6, 2017

SIEMENS HEALTHCARE DIAGNOSTICS, INC.
LAURA J. DUGGAN, Ph.D., RAC
REGULATORY TECHNICAL SPECIALIST
500 GBC DRIVE, PO BOX 6101 MS 514
NEWARK DE 19711

Re: k163220
Trade/Device Name: Atellica CH Phencyclidine (Pcp)
Regulation Number: Unclassified
Regulation Name: Enzyme Immunoassay, Phencyclidine
Regulatory Class: Unclassified, 510(k) required
Product Code: LCM
Dated: February 14, 2017
Received: February 15, 2017

Dear Dr. Laura Duggan:

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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

Courtney H. Lias -S

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

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)*

k163220

Device Name
Atellica CH Phencyclidine (Pcp)

Indications for Use *(Describe)*

The Atellica™ CH Phencyclidine (Pcp) assay is for in vitro diagnostic use in the qualitative or semiquantitative analyses of phencyclidine in human urine using the Atellica CH Analyzer, using a cutoff of 25 ng/mL. The Pcp assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. 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. Clinical consideration and professional judgment should be applied to any drug-of-abuse 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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10. 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

ASSIGNED 510(K) NUMBER

The assigned 510(k) number is k163220.

APPLICANT AND DATE

Laura J. Duggan, Ph. D., RAC
Siemens Healthcare Diagnostics Inc.
500 GBC Drive, M/S 514
Newark, DE 19714-6101
Email: laura.j.duggan@siemens.com
Phone: 302-631-7654
Fax: 302-631-6299

March 10, 2017

MANUFACTURER

Siemens Healthcare Diagnostics Inc.
511 Benedict Ave
Tarrytown, NY 10591
Registration Number: 2432235

REGULATORY INFORMATION

Regulatory Submission for the Atellica™ CH Phencyclidine (Pcp)

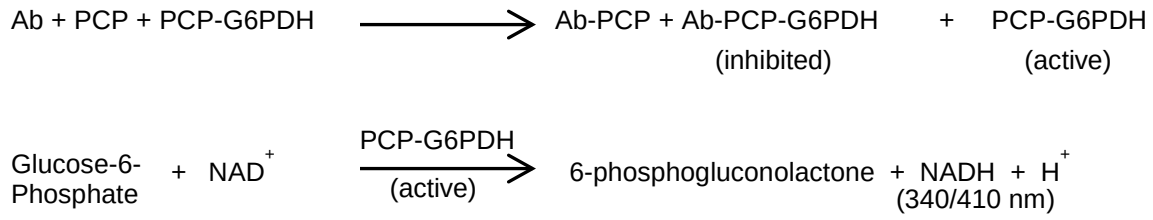
Common Name:	enzyme immunoassay, phencyclidine
Proprietary Name:	Atellica CH Phencyclidine (Pcp)
Classification Name:	Enzyme Immunoassay, Phencyclidine
Regulation Number:	Unclassified
Classification:	Unclassified, 510(k) required
Product Code:	LCM
Panel:	Toxicology
Predicate Device:	URINE PHENCYCLIDINE (PCP) SCREEN FLEX REAGENT CARTRIDGE (k000462)

DEVICE DESCRIPTION

ATELLICA CH PHENCYCLIDINE (PCP)

The Atellica CH Pcp assay is a homogenous enzyme immunoassay based on competition between drug in the specimen and drug labeled with glucose-6-phosphate dehydrogenase (G6PDH) for antibody binding sites. G6PDH activity decreases upon binding to the antibody, so the drug concentration in the specimen can be measured in terms of enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD+) to NADH in the presence of glucose-6-phosphate (G6P), resulting in an absorbance change that is measured spectrophotometrically at 340/410 nm.

Reaction Equation



Where: Ab = antibody reactive to phencyclidine
PCP = phencyclidine
PCP-G6PDH = phencyclidine conjugated to recombinant glucose-6-phosphate dehydrogenase

Urine is the only specimen type. The reagent is stored unopened at 2 – 8 °C and is stable for use on system for 30 days. Calibration is performed every 60 days for a reagent lot or every 19 days for an individual pack.

INTENDED USE/INDICATIONS FOR USE

ATELLICA CH PHENCYCLIDINE (PCP)

The Atellica™ CH Phencyclidine (Pcp) assay is for in vitro diagnostic use in the qualitative or semiquantitative analyses of phencyclidine in human urine using the Atellica CH Analyzer, using a cutoff of 25 ng/mL. The Pcp assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. 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. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Below is a features comparison for the Atellica CH Phencyclidine (Pcp) assay and the predicate device:

Feature	**Predicate Device:** URINE PHENCYCLIDINE (PCP) SCREEN FLEX REAGENT CARTRIDGE (k000462)	**New Device:** Atellica CH Phencyclidine (Pcp)
Intended Use :	The Urine Phencyclidine Screen Flex® reagent cartridge used on the Dimension® clinical chemistry system provides reagents for an *in vitro* diagnostic test intended for the qualitative and semi-quantitative determination of phencyclidine in human urine. Measurements obtained with the PCP method are used in the diagnosis and treatment of phencyclidine use or overdose. The PCP method 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) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.	The Atellica™ CH Phencyclidine (Pcp) assay is for in vitro diagnostic use in the qualitative or semiquantitative analyses of phencyclidine in human urine using the Atellica™ CH Analyzer. The Pcp assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. 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 (LCMS/MS) or permitting laboratories to establish quality control procedures. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

Type of Product:	Analytical Reagents	Same
Measured Analyte:	PCP	Same
Test Matrix:	Urine	Same
Device Technology:	Enzyme Immunoassay	Same
Materials:	Matched lots of polyclonal antibody reactive to phencyclidine and phencyclidine labeled with glucose-6-phosphate dehydrogenase are used in this Syva® Emit® II Plus methodology.	Same
Cutoff Levels:	25 ng/mL PCP	Same
Confirmatory Method:	Gas Chromatography/mass spectrometry	Same
Calibration Frequency:	30 days	60 days

SUMMARY OF PERFORMANCE TESTING

Assay performance comparison results for the Atellica CH Phencyclidine (Pcp) were obtained by processing the appropriate body fluids. Summary statistics for each are provided. These data demonstrate substantial equivalency of the Atellica CH Phencyclidine (Pcp) compared to the predicate device. The following data represent typical assay performance.

PRECISION/CUTOFF CHARACTERIZATION

Precision was determined according to the CLSI Document EP05-A3. The study was performed for 20 days, 2 runs per day with 2 replicates (N=80) on concentrations of ±25%, ±50%, ±75% and ±100% of the cutoff. The study verified that the cutoff serves as a boundary between a negative and positive interpretation of a qualitative result.

a) The following is summary table of the Qualitative Analysis for the 25 ng/mL cutoff test data results.

Qualitative Analysis (25 ng/mL cutoff)			
[Urine Pool] (ng/mL)	% of Cutoff	# of Results	Result
0	-100	80	80 Negative
6.25	-75	80	80 Negative
12.5	-50	80	80 Negative
18.75	-25	80	80 Negative
25	Cutoff	80	60 Positive / 20 Negative
31.25	25	80	80 Positive
37.5	50	80	80 Positive
43.75	75	80	80 Positive
50	100	80	80 Positive

b) The following is summary table of the semi-quantitative analysis for the 25 ng/mL cutoff test data results.

Semi-quantitative Analysis (25 ng/mL cutoff)									
Urine Pool (ng/mL)	% of Cutoff	# of Results	Mean (ng/mL)	Repeatability		Within-Lab		Repeatability Results	Within-Laboratory Results
				SD (ng/mL)	CV (%)	SD (ng/mL)	CV (%)		
0	-100	80	0	0	N/A	1	N/A	80 Negative	80 Negative
6.25	-75	80	7	0	3.8	1	7.7	80 Negative	80 Negative
12.5	-50	80	12	0	2.2	0	4.0	80 Negative	80 Negative
18.75	-25	80	18	0	1.8	1	3.3	80 Negative	80 Negative
25	Cutoff	80	25	0	1.6	1	3.4	60 Positive / 20 Negative	60 Positive / 20 Negative
31.25	25	80	30	1	2.2	1	2.7	80 Positive	80 Positive
37.5	50	80	37	1	1.4	1	3.3	80 Positive	80 Positive
43.75	75	80	43	1	1.5	2	4.6	80 Positive	80 Positive
50	100	80	51	1	1.3	2	4.5	80 Positive	80 Positive

RECOVERY STUDY

A drug free urine pool was spiked with high concentration PCP analyte stock to various target values.

Sample ID	Spiked Pcp (ng/mL)	Mean Pcp (ng/mL)	% Recovery
1	4.0	4.3	107.5
2	5.0	5.6	112.0
3	10.0	10.1	101.0
4	15.0	15.0	100.0
5	20.0	19.7	98.5
6	25.0	25.1	100.4
7	30.0	30.0	100.0
8	40.0	41.0	102.5
9	60.0	60.9	101.5
10	80.0	83.7	104.6

METHOD COMPARISON

Anonymous, discarded clinical urine samples were analyzed with the test device. Method Comparison was tested by comparison to the reference method, which is GC/MS. Six samples were prepared by pooling two native urine samples to span the assay measuring interval. All of the remaining samples were unaltered native samples.

a) Summary of Qualitative Results

		GC/MS	
		(+)	(-)
Atellica	(+)	53	1
	(-)	3	55

b) Summary of the Qualitative Assay Performance for the 25 ng/mL cutoff

	GC/MS Results				
Atellica	Neg (< 13 ng/mL)	Neg Within 50% below the cutoff (13 - 24 ng/mL)	Pos Within 50% above the cutoff (25 - 38 ng/mL)	Pos (> 38 ng/mL)	% Agreement
Qualitative					
Atellica Pos	0	1	17	36	98%
Atellica Neg	48	7	3	0	95%

c) Summary of Semi-Quantitative Results

		GC/MS	
		(+)	(-)
Atellica	(+)	53	1
	(-)	3	55

d) Summary of the Semi-Quantitative Assay Performance for the 25 ng/mL cutoff

	GC/MS Results				
Atellica	Neg (< 13 ng/mL)	Neg Within 50% below the cutoff (13 - 24 ng/mL)	Pos Within 50% above the cutoff (25 - 38 ng/mL)	Pos (> 38 ng/mL)	% Agreement
Semi-Quantitative					
Atellica Pos	0	1	17	36	98%
Atellica Neg	48	7	3	0	95%

e) Summary of Discordant Results

Sample ID	Atellica CH (ng/mL)	GC/MS (ng/mL)	Atellica CH vs. GC/MS (POS/NEG)
53	25	23.7	+/-

57	23	25.3	-/+
59	23	28.2	-/+
61	22	30.0	-/+

INTERFERENCES

Interference was determined in accordance with CLSI Document EP07-A2. Structurally non-similar compounds, endogenous compounds, the effect of pH, the effect of specific gravity and boric acid were evaluated by spiking the potential interferent into drug free urine containing the target analyte at ±25% of the cutoff. All potential interferents analyzed verified that the assay performance is unaffected by externally ingested compounds or an internally existing physiological conditions. Any test compound that was shown to produce a false response at the test concentration optionally underwent does-response testing until a false response was not obtained.

a) Summary of the Effect of pH

pH Value	-25% Cutoff (19 ng/mL)		+25% Cutoff (31 ng/mL)	
	Result	Intereference?	Result	Intereference?
3.1	Negative	No	Positive	No
4.0	Negative	No	Positive	No
5.0	Negative	No	Positive	No
6.0	Negative	No	Positive	No
7.0	Negative	No	Positive	No
8.0	Negative	No	Positive	No
9.0	Negative	No	Positive	No
10.1	Negative	No	Positive	No
11.0	Negative	No	Positive	No

b) Summary of the Effect of Specific Gravity

sG	-25% Cutoff Pool Result (19 ng/mL)	Intereference?	+25% Cutoff Pool Result (31 ng/mL)	Intereference?
1.000	Negative	No	Positive	No
1.002	Negative	No	Positive	No
1.005	Negative	No	Positive	No
1.010	Negative	No	Positive	No
1.015	Negative	No	Positive	No
1.020	Negative	No	Positive	No
1.025	Negative	No	Positive	No
1.030	Negative	No	Positive	No

c) Summary of the Effect of Endogenous Compounds

At the stated concentration, the sample did not give a false response relative to the 25 ng/mL cutoff.

Compound	Concentration Tested	-25% of Cutoff (19 ng/mL)	+25% of Cutoff (31 ng/mL)
Acetone	1.0 g/dL	Negative	Positive
Ascorbic Acid	0.75 g/dL	Negative	Positive
Conjugated bilirubin	0.25 mg/dL	Negative	Positive
Creatinine	0.5 g/dL	Negative	Positive
Ethanol	1.0 g/dL	Negative	Positive
Gamma Globulin	0.5 g/dL	Negative	Positive
Galactose	0.01 g/dL	Negative	Positive
Glucose	2.0 g/dL	Negative	Positive
Hemoglobin	115 mg/dL	Negative	Positive
Human Serum Albumin	0.5 g/dL	Negative	Positive
Oxalic Acid	0.1 g/dL	Negative	Positive
Riboflavin	7.5 mg/dL	Negative	Positive
Sodium Azide	1% (*w/v*)	Negative	Positive
Sodium Chloride	1.5 g/dL	Negative	Positive
Sodium Fluoride	1% (*w/v*)	Negative	Positive
Urea	6.0 g/dL	Negative	Positive

d) Summary of the Effect of Structurally Unrelated Compounds

At the stated concentration, the sample did not give a false response relative to the 25 ng/mL cutoff.

Compound	Concentration Tested (ng/mL)	-25% of Cutoff (19 ng/mL)	+25% of Cutoff (31 ng/mL)
Acetaminophen	500,000	Negative	Positive
I-α-Acetylmethadol (LAAM)	25,000	Negative	Positive
N-Acetyl procainamide (NAPA)	100,000	Negative	Positive
Acetylsalicylic Acid	500,000	Negative	Positive
Amitriptyline	8,750	Negative	Positive
S-(+)-Amphetamine	100,000	Negative	Positive
Benzoylecgonine	100,000	Negative	Positive
Buprenorphine	100,000	Negative	Positive
Caffeine	500,000	Negative	Positive
Cannabinol	100,000	Negative	Positive
Carbamazepine	100,000	Negative	Positive
Chlordiazepoxide	100,000	Negative	Positive
Cimetidine	100,000	Negative	Positive
Clonidine	100,000	Negative	Positive
Codeine	25,000	Negative	Positive
Cotinine	100,000	Negative	Positive
Desipramine	75,000	Negative	Positive
Dextrorphan	781	Negative	Positive
Diazepam	100,000	Negative	Positive
Digoxin	100,000	Negative	Positive
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	12,500	Negative	Positive
EMDP	100,000	Negative	Positive
1R,2S-Ephedrine	100,000	Negative	Positive
1S,2R-Ephedrine	100,000	Negative	Positive
Fluoxetine	75,000	Negative	Positive
Flurazepam	50,000	Negative	Positive
Glutethimide	100,000	Negative	Positive
Haloperidol	100,000	Negative	Positive
Heroin	25,000	Negative	Positive
Hydrocodone	25,000	Negative	Positive
Ibuprofen	500,000	Negative	Positive
Ketamine	75,000	Negative	Positive
Ketorolac Tromethamine	100,000	Negative	Positive
Lidocaine	100,000	Negative	Positive
Lorazepam	100,000	Negative	Positive
Lormetazepam	100,000	Negative	Positive
LSD	100,000	Negative	Positive
MDMA	100,000	Negative	Positive
Meperidine	1,563	Negative	Positive
Methadone	50,000	Negative	Positive

Compound	Concentration Tested (ng/mL)	-25% of Cutoff (19 ng/mL)	+25% of Cutoff (31 ng/mL)
S(+) - Methamphetamine	100,000	Negative	Positive
Methaqualone	100,000	Negative	Positive
Morphine	75,000	Negative	Positive
Naproxen	100,000	Negative	Positive
Nordiazepam	100,000	Negative	Positive
Nortriptyline	75,000	Negative	Positive
Oxazepam	100,000	Negative	Positive
Oxycodone	100,000	Negative	Positive
Phenobarbital	100,000	Negative	Positive
Phenylephrine	100,000	Negative	Positive
Phenytoin	100,000	Negative	Positive
Promethazine	3,125	Negative	Positive
Propoxyphene	100,000	Negative	Positive
Propranolol	100,000	Negative	Positive
Protriptyline	75,000	Negative	Positive
R,R - Pseudoephedrine	100,000	Negative	Positive
S,S - Pseudoephedrine	100,000	Negative	Positive
Ranitidine	100,000	Negative	Positive
Ritalinic Acid	100,000	Negative	Positive
Salicylic Acid	100,000	Negative	Positive
Scopolamine	100,000	Negative	Positive
Secobarbital	100,000	Negative	Positive
Tapentadol	50,000	Negative	Positive
11-nor-Δ9-THC-9-COOH	100,000	Negative	Positive
Tramadol	50,000	Negative	Positive
Trazodone	100,000	Negative	Positive
Tyramine	100,000	Negative	Positive
Verapamil	60,000	Negative	Positive
Zidovudine (AZT)	100,000	Negative	Positive
Zolpidem	100,000	Negative	Positive

Boric acid results in a false negative result. The package insert notifies the user of this limitation.

CROSS-REACTIVITY

Specificity was determined in accordance with CLSI Document EP07-A2. Structurally similar compounds were spiked into drug free urine at the levels indicated. Cross-reactivity was calculated.

Summary of Cross-reactivity:

Test Compound	Concentration Tested (ng/mL)	Cross-Reactivity (%)
Chloropromazine	100000	0.02
Clomipramine	100000	0.02
Cyclobenzaprine	25000	0.03
Dextromethorphan	80000	0.02
Diphenhydramine	100000	0.01
Doxepin	90000	0.01
Imipramine	100000	0.01
Methoxetamine	36000	0.03
4-Methoxyphencyclidine	700	8.43
Thioridazine	100000	0.04
Venlafaxine	100000	0.01
1-(4-Hydroxypiperidino)phenylcyclohexane	419	5.97
1-(1-Phenylcyclohexyl)pyrrolidine (PCPy)	54	38.33
1-[1-(2-Thienyl)-cyclohexyl]piperidine (TCP)	37	58.11
trans-4-phenyl-4-Piperidinocyclohexanol	32	74.38

CONCLUSION

The Atellica CH Phencyclidine (Pcp) is substantially equivalent to the Urine Phencyclidine Screen Flex® reagent cartridge used on the Dimension clinical chemistry system in principle and performance based on the similarity of device designs and function demonstrated through method comparison and other performance attributes.