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

October 18, 2017

SIEMENS HEALTHCARE DIAGNOSTICS INC.
ALAN HALEY
REGULATORY AND CLINICAL AFFAIRS SPECIALIST
500 GBC DRIVE, M/S 514
NEWARK, DE 19702

Re: k172910
Trade/Device Name: Emit II Plus Oxycodone Assay
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG
Dated: September 21, 2017
Received: September 25, 2017

Dear Alan Haley:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k172910

Device Name
Emit II Plus Oxycodone Assay

Indications for Use *(Describe)*
The Emit II Plus Oxycodone Assay is a homogeneous enzyme immunoassay with 100 ng/mL and 300 ng/mL cutoffs. The assay is intended for in vitro diagnostic use in the qualitative and semiquantitative determination of oxycodone in human urine. The Emit II Plus Oxycodone Assay is designed for use with a number of clinical chemistry analyzers. The semiquantitative mode is for the purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Liquid Chromatography/Mass Spectrometry (LC/MS) or permitting laboratories to establish quality control procedures.

The Emit II Plus Oxycodone Assay provides only a preliminary analytical test result. A more specific alternative chemical method(s) must be used to obtain a confirmed analytical test result. Gas Chromatography/Mass Spectrometry (GC/MS) and LC/MS are the preferred confirmatory methods. Clinical consideration and professional judgement 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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510(k) Summary

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of Safe Medical Device Act of 1990 and 21 CFR 807.92.

1. Submitter

Company Siemens Healthcare Diagnostics Inc.

Address 500 GBC Drive, M/S 514 Newark, DE 19702

Contact Alan Haley

Telephone 302.631.9883

Fax 302.631.6299

Date of Preparation October 16, 2017

2. Device Information

Trade Name	Emit® II Plus Oxycodone Assay
Common Name	Enzyme Immunoassay, Opiates
Classification Name	Opiate Test System
Regulation	21 CFR 862.3650
Device Class	Class II
Product Code	DJG

3. Identification of Predicate

Trade Name	DRI Oxycodone Assay
510(k) Submitter	Microgenics Corp.
510(k) Number	K040411
Clearance Date	May 27, 2004

4. Device Description

The Emit® II Plus Oxycodone assay is a homogeneous enzyme immunoassay with 100 ng/mL and 300 ng/mL cutoffs. The assay, used for the detection of oxycodone in human urine, utilizes a two- reagent system. The Antibody/Substrate Reagent 1 is a liquid ready-to-use product comprised of mouse monoclonal antibodies to oxycodone, glucose-6-phosphate (G6P), and nicotinamide adenine dinucleotide (NAD) in a diluent containing bovine serum albumin (BSA), preservatives and stabilizers. The Enzyme Reagent 2 is a liquid, ready-to-use product containing oxymorphone labeled with bacterial recombinant glucose-6 phosphate dehydrogenase (rG6PDH) in a diluent containing bovine serum albumin (BSA), HEPES buffer, preservatives and stabilizers.

The assay kit consists of Reagent 1 and Reagent 2 in plastic containers and is available in three sizes: 1000 mL/500 mL, 115 mL/50 mL, and 28 mL/14 mL. Emit® II Plus assays are designed for use with a number of chemistry analyzers. The Emit® II Plus Oxycodone assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result.

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5. Intended Use Statement

The Emit® II Plus Oxycodone Assay is a homogeneous enzyme immunoassay with 100 ng/mL and 300 ng/mL cutoffs. The assay is intended for in vitro diagnostic use in the qualitative and semiquantitative determination of oxycodone in human urine. The Emit® II Plus Oxycodone Assay is designed for use with a number of clinical chemistry analyzers. The semiquantitative mode is for the purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Liquid Chromatography/Mass Spectrometry (LC/MS) or permitting laboratories to establish quality control procedures.

The Emit® II Plus Oxycodone Assay provides only a preliminary analytical test result. A more specific alternative chemical method(s) must be used to obtain a confirmed analytical test result. Gas Chromatography/Mass Spectrometry (GC/MS) and LC/MS are the preferred confirmatory methods. Clinical consideration and professional judgement should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

6. Technological Characteristics

(a) Comparison to Predicate

Item	DRI Oxycodone Assay (K040411)	Emit® II Plus Oxycodone Assay (Proposed)
Intended Use	The DRI® Oxycodone assay is intended to be used for the qualitative and semi-quantitative determination of the presence of oxycodone in human urine at cutoffs of 100 ng/mL and 300 ng/mL.	Same
Analyte	Oxycodone	Same
Matrix	Urine	Same
Storage	2°C to 8°C until expiration date	Same
Type of Test	Homogeneous enzyme immunoassay	Same
Reagent Form	Liquid, Ready to Use	Same
Reagent Composition	Antibody/substrate reagent and enzyme conjugate/reagent. The antibody substrate reagent includes mouse monoclonal anti-oxycodone derivative antibody, glucose-6-phosphate and NAD in buffer with preservative. The enzyme conjugate reagent includes oxycodone derivative labeled with glucose-6-phosphate dehydrogenase in buffer with preservative.	Same
Cutoffs	100 ng/mL oxycodone 300 ng/mL oxycodone	Same

(b) Non-Clinical Performance Evaluation

The data that appear in this section were collected on the Viva-E® Analyzer using the Emit® II Plus Oxycodone Assay. Summary results for each study are provided. The results represent typical assay performance.

(i) Method Comparison

A total of 100 unaltered native patient samples were tested for each cutoff. Samples were evaluated using the Emit® II Plus Oxycodone Assay on the Viva-E® instrument and Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS).

Results for the 100 ng/mL assay cutoff are presented below:

Table A. Method Comparison Results (100 ng/mL Cutoff)

		LC-MS/MS			
		Low Negative (Less than 50% below the cutoff concentration)	**Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)**	**Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)**	**High Positive (greater than 50% above the cutoff concentration)**
		Qualitative Mode			
Emit®	**Positive**	0	0	9	43
	Negative	31	13	4	0
		Agreement among positives is 52/56 = 93% Agreement among negatives is 44/44 = 100%			
		Semiquantitative Mode			
Emit®	**Positive**	0	0	9	43
	Negative	31	13	4	0
		Agreement among positives is 52/56 = 93% Agreement among negatives is 44/44 = 100%			

Table B. Discordant Results (100 ng/mL Cutoff)

Sample #	**Emit®**		**LC-MS/MS**	
	Semiquantitative (ng/mL)	**Qualitative (Pos/Neg)**	**Oxycodone (ng/mL)**	**Oxymorphone (ng/mL)**
OXY-471	85	Neg	100	0
OXY-9128	90	Neg	102	0
OXY-9129	96	Neg	103	0
OXY-9130	93	Neg	103	0

Results for the 300 ng/mL assay cutoff are presented below.

Table C. Method Comparison Results (300 ng/mL Cutoff)

		LC-MS/MS			
		Low Negative (Less than 50% below the cutoff concentration)	**Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration))**	**Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)**	**High Positive (greater than 50% above the cutoff concentration)**
		Qualitative Mode			
Emit®	**Positive**	0	1	11	33
	Negative	42	12	1	0
		Agreement among positives is 44/45 = 98% Agreement among negatives is 54/55 = 98%			
		Semiquantitative Mode			
Emit®	**Positive**	0	0	11	33
	Negative	42	13	1	0
		Agreement among positives is 44/45 = 98% Agreement among negatives is 55/55 = 100%			

Table D. Discordant Results (300 ng/mL Cutoff)

Sample #	**Emit®**		**LC-MS/MS**	
	Semiquantitative (ng/mL)	**Qualitative (Pos/Neg)**	**Oxycodone (ng/mL)**	**Oxymorphone (ng/mL)**
OXY-161	263	Neg	318	0
OXY-665	288	Pos	182	29.1

(ii) Precision

Repeatability and Within-Lab Precision were determined by assaying urine pools spiked with oxycodone at nine different levels for each cutoff. The testing sequence for each level consisted of two replicates, twice a day, for twenty days (n = 80) for each cutoff. Precision data were evaluated according to the Clinical and Laboratory Standards Institute (CLSI) Guideline EP05-A3.

Table E. Precision (100 ng/mL Cutoff)

Urine Pool (ng/mL)	**% of Cutoff**	**# of Results**	**Qualitative**		**Semiquantitative**	
			Repeatability	**Within-Lab**	**Repeatability**	**Within-Lab**
0	-100	80	80 Negative	80 Negative	80 Negative	80 Negative
25	-75	80	80 Negative	80 Negative	80 Negative	80 Negative
50	-50	80	80 Negative	80 Negative	80 Negative	80 Negative
75	-25	80	80 Negative	80 Negative	80 Negative	80 Negative
100	Cutoff	80	2 Negative/ 78 Positive	2 Negative/ 78 Positive	2 Negative/ 78 Positive	2 Negative/ 78 Positive
125	+25	80	80 Positive	80 Positive	80 Positive	80 Positive
150	+50	80	80 Positive	80 Positive	80 Positive	80 Positive
175	+75	80	80 Positive	80 Positive	80 Positive	80 Positive
200	+100	80	80 Positive	80 Positive	80 Positive	80 Positive

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Table F. Precision (300 ng/mL cutoff)

Urine Pool (ng/mL)	% of Cutoff	# of Results	Qualitative		Semiquantitative	
			Repeatability	Within-Lab	Repeatability	Within-Lab
0	-100	80	80 Negative	80 Negative	80 Negative	80 Negative
75	-75	80	80 Negative	80 Negative	80 Negative	80 Negative
150	-50	80	80 Negative	80 Negative	80 Negative	80 Negative
225	-25	80	80 Negative	80 Negative	80 Negative	80 Negative
300	Cutoff	80	4 Negative/ 76 Positive	4 Negative/ 76 Positive	16 Negative/ 64 Positive	16 Negative/ 64 Positive
375	+25	80	80 Positive	80 Positive	80 Positive	80 Positive
450	+50	80	80 Positive	80 Positive	80 Positive	80 Positive
525	+75	80	80 Positive	80 Positive	80 Positive	80 Positive
600	+100	80	80 Positive	80 Positive	80 Positive	80 Positive

(iii) Recovery

Oxycodone samples were prepared by spiking known levels of oxycodone into drug-free urine. A total of 7 concentrations were evaluated for oxycodone at the 100 ng/mL cutoff and 13 concentrations were evaluated for oxycodone at the 300 ng/mL cutoff. Spiked samples were analyzed in replicates of 5. Results are shown in Table G for the 100 ng/mL cutoff; Table H for the 300 ng/mL cutoff.

Table G. Recovery Results (100 ng/mL Cutoff)

Target Concentration (ng/mL)	Mean Measured Concentration (ng/mL)	Mean Recovery (%)
50	60	120
75	79	105
100	96	96
125	123	98
200	196	98
300	306	102
400	385	96

Table H. Recovery Results (300 ng/mL Cutoff)

Target Concentration (ng/mL)	Mean Measured Concentration (ng/mL)	Mean Recovery (%)
100	101	101
150	145	97
200	191	96
225	216	96
300	304	101
375	374	100
400	414	104
500	525	105
600	621	104
700	723	103
800	803	100
900	893	99
1000	969	97

(iv) Oxycodone Metabolites

Oxycodone metabolites were spiked into negative urine and evaluated by dose-response to determine the level that would give a response approximately equivalent to the cutoff response. Percent cross-reactivity was calculated according to CLSI EP07-A2.

Table I. Oxycodone Metabolite Cross-Reactivity (100 ng/mL cutoff)

Compound	Concentration (ng/mL)	% Cross-Reactivity
Oxycodone	100	100.0
Oxymorphone	119	84.0
Oxymorphone-3-β-glucuronide	1,700	5.9
Noroxycodone	11,000	0.9
Noroxymorphone	31,000	0.3

Table J. Oxycodone Metabolite Cross-Reactivity (300 ng/mL cutoff)

Compound	Concentration (ng/mL)	% Cross-Reactivity
Oxycodone	310	96.8
Oxymorphone	400	75.0
Oxymorphone-3-β-glucuronide	5,800	5.2
Noroxycodone	35,000	0.9
Noroxymorphone	81,000	0.4

(v) Structurally Related Compounds

Structurally similar drugs were spiked into drug-free urine and percent cross-reactivity was evaluated at both cutoffs according to CLSI EP07-A2. Drugs eliciting a positive response were evaluated by dose-response to determine the lowest level of cross-reactant that would generate a positive result relative to the cutoff.

Table K. Structurally Related Compounds (100 ng/mL Cutoff)

Compound	Concentration (ng/mL)	% Cross-Reactivity
6-Acetylcodeine	100,000	0.01
6-Acetylmorphine	100,000	0.01
Buprenorphine	100,000	0.01
Codeine	340,000	0.03
Dextromethorphan	200,000	<0.01
Dihydrocodeine	100,000	0.02
Heroin	300,000	0.01
Hydrocodone	1,000,000	<0.01
Hydromorphone	1,000,000	<0.01
Levorphanol	200,000	<0.01
Morphine	1,000,000	<0.01
Morphine 3-β-D-glucuronide	1,000,000	<0.01
Nalorphine	100,000	0.02
Naloxone	16,000	0.63
Naltrexone	500,000	0.02
Norcodeine	1,000,000	<0.01
Normorphine	1,000,000	<0.01

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Table L. Structurally Related Compounds (300 ng/mL Cutoff)

Compound	Concentration (ng/mL)	% Cross-reactivity
6-Acetylcodeine	100,000	<0.01
6-Acetylmorphine	100,000	0.02
Buprenorphine	100,000	<0.01
Codeine	1,000,000	0.03
Dextromethorphan	200,000	<0.01
Dihydrocodeine	100,000	0.02
Heroin	300,000	<0.01
Hydrocodone	1,000,000	<0.01
Hydromorphone	1,000,000	<0.01
Levorphanol	200,000	<0.01
Morphine	1,000,000	<0.01
Morphine 3-β-D-glucuronide	1,000,000	<0.01
Nalorphine	100,000	0.02
Naloxone	46,000	0.65
Naltrexone	500,000	0.02
Norcodeine	1,000,000	<0.01
Normorphine	1,000,000	<0.01

(vi) Structurally Unrelated Compounds

The interference of structurally unrelated compounds and common over the counter drugs was evaluated qualitatively and semiquantitatively according to CLSI EP07-A2 at the concentrations listed below. For each cutoff, the compounds were spiked into two levels of controls at +/- 25% of the cutoff concentration. At the stated concentration, the sample did not give a false response relative to the 100 ng/mL or 300 ng/mL cutoffs.

Table M. Structurally Unrelated Compounds (100 ng/mL and 300 ng/mL Cutoffs)

Compound	Concen-tration (µg/mL)	100 ng/mL Cutoff		300 ng/mL Cutoff	
		-25% Control (75 ng/mL)	+25% Control (125 ng/mL)	-25% Control (225 ng/mL)	+25% Control (375 ng/mL)
10, 11-Dihydrocarbamazepine	85	Negative	Positive	Negative	Positive
Acetaminophen	1,000	Negative	Positive	Negative	Positive
Acetylsalicylic Acid	1,500	Negative	Positive	Negative	Positive
Amitriptyline	100	Negative	Positive	Negative	Positive
Amoxicillin	500	Negative	Positive	Negative	Positive
AZT (Zidovudine)	2,000	Negative	Positive	Negative	Positive
Benzoylecgonine	1,000	Negative	Positive	Negative	Positive
Brompheniramine	75	Negative	Positive	Negative	Positive
Caffeine	1,000	Negative	Positive	Negative	Positive
Captopril	500	Negative	Positive	Negative	Positive
Chlordiazepoxide	100	Negative	Positive	Negative	Positive
Chlorpromazine	10	Negative	Positive	Negative	Positive
Cimetidine	1,000	Negative	Positive	Negative	Positive
Clomipramine	2.5	Negative	Positive	Negative	Positive
Clonidine	1,000	Negative	Positive	Negative	Positive
Cyclobenzaprine	125	Negative	Positive	Negative	Positive
d-Amphetamine	700	Negative	Positive	Negative	Positive
Desipramine	800	Negative	Positive	Negative	Positive
Diazepam	100	Negative	Positive	Negative	Positive

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Compound	Concen-tration (µg/mL)	100 ng/mL Cutoff		300 ng/mL Cutoff	
		-25% Control (75 ng/mL)	+25% Control (125 ng/mL)	-25% Control (225 ng/mL)	+25% Control (375 ng/mL)
Digoxin	0.01	Negative	Positive	Negative	Positive
Diphenhydramine	1,000	Negative	Positive	Negative	Positive
d-Methamphetamine	500	Negative	Positive	Negative	Positive
Doxepine	100	Negative	Positive	Negative	Positive
EDDP	1,000	Negative	Positive	Negative	Positive
EMDP	100	Negative	Positive	Negative	Positive
Enalapril	500	Negative	Positive	Negative	Positive
Fentanyl	200	Negative	Positive	Negative	Positive
Fluoxetine	500	Negative	Positive	Negative	Positive
Glutethimide	500	Negative	Positive	Negative	Positive
Haloperidol	100	Negative	Positive	Negative	Positive
Hydroxyzine	500	Negative	Positive	Negative	Positive
Ibuprofen	1,000	Negative	Positive	Negative	Positive
Imipramine	200	Negative	Positive	Negative	Positive
Ketamine	100	Negative	Positive	Negative	Positive
Ketorolac Tromethamine	400	Negative	Positive	Negative	Positive
LAAM (L-a-Acetylmethadol)	25	Negative	Positive	Negative	Positive
L-Cotinine	100	Negative	Positive	Negative	Positive
Levofloxacin	100	Negative	Positive	Negative	Positive
Levothyroxine (L- Thyroxine)	50	Negative	Positive	Negative	Positive
Lidocaine	1,000	Negative	Positive	Negative	Positive
Lormetazepam	1	Negative	Positive	Negative	Positive
LSD	10	Negative	Positive	Negative	Positive
MDMA (Ecstasy)	1,000	Negative	Positive	Negative	Positive
Meperidine	800	Negative	Positive	Negative	Positive
Methadone	500	Negative	Positive	Negative	Positive
Methaqualone	600	Negative	Positive	Negative	Positive
NAPA (N-Acetylprocainamide)	400	Negative	Positive	Negative	Positive
Naproxen	1,000	Negative	Positive	Negative	Positive
Nicotinic Acid	500	Negative	Positive	Negative	Positive
Nifedipine	500	Negative	Positive	Negative	Positive
Nordiazepam	100	Negative	Positive	Negative	Positive
Nortryptiline	250	Negative	Positive	Negative	Positive
Oxazepam	300	Negative	Positive	Negative	Positive
Perphenazine	150	Negative	Positive	Negative	Positive
Phencyclidine	1,000	Negative	Positive	Negative	Positive
Phenobarbital	500	Negative	Positive	Negative	Positive
Phenelzine	100	Negative	Positive	Negative	Positive
Phenytoin	1,000	Negative	Positive	Negative	Positive
Procainamide	1,000	Negative	Positive	Negative	Positive
Procyclidine	800	Negative	Positive	Negative	Positive
Promethazine	100	Negative	Positive	Negative	Positive
Propoxyphene	1,000	Negative	Positive	Negative	Positive
Protriptyline	200	Negative	Positive	Negative	Positive
Pseudoephedrine	1,000	Negative	Positive	Negative	Positive
Quinacrine	1,000	Negative	Positive	Negative	Positive
Ranitidine	1,000	Negative	Positive	Negative	Positive

Compound	Concen-tration (µg/mL)	100 ng/mL Cutoff		300 ng/mL Cutoff	
		-25% Control (75 ng/mL)	+25% Control (125 ng/mL)	-25% Control (225 ng/mL)	+25% Control (375 ng/mL)
Ritalin (Methylphenidate)	1,000	Negative	Positive	Negative	Positive
Salicylic Acid	500	Negative	Positive	Negative	Positive
Scopolamine	500	Negative	Positive	Negative	Positive
Secobarbital	1,000	Negative	Positive	Negative	Positive
Tapentadol	100	Negative	Positive	Negative	Positive
THC (11-nor-9-Carboxy-Δ9-THC)	100	Negative	Positive	Negative	Positive
Thioridazine	100	Negative	Positive	Negative	Positive
Tramadol	1,000	Negative	Positive	Negative	Positive
Trazodone	5	Negative	Positive	Negative	Positive
Trimethoprim	1,000	Negative	Positive	Negative	Positive
Triprolidine (zymine)	50	Negative	Positive	Negative	Positive
Tyramine	100	Negative	Positive	Negative	Positive
Verapamil	500	Negative	Positive	Negative	Positive
Zolpidem	100	Negative	Positive	Negative	Positive

(vii) Endogenous Substances

Endogenous substances were evaluated qualitatively and semiquantitatively according to CLSI EP07-A2 at the concentrations listed below. The compounds were spiked into two levels of controls at +/- 25% of the cutoff concentration for each cutoff. At the stated concentrations, the sample did not give a false response relative to the 100 ng/mL or 300 ng/mL cutoffs.

Table N. Endogenous Substances (100 ng/mL and 300 ng/mL Cutoffs)

Compound	Concen-tration	100 ng/mL Cutoff		300 ng/mL Cutoff	
		-25% Control (75 ng/mL)	+25% Control (125 ng/mL)	-25% Control (225 ng/mL)	+25% Control (375 ng/mL)
Acetone	1.0 g/dL	Negative	Positive	Negative	Positive
Ascorbic Acid	1.5 g/dL	Negative	Positive	Negative	Positive
Conjugated Bilirubin	2.0 mg/dL	Negative	Positive	Negative	Positive
Unconjugated Bilirubin	2.0 mg/dL	Negative	Positive	Negative	Positive
Creatinine	0.5 g/dL	Negative	Positive	Negative	Positive
Ethanol	1.0 g/dL	Negative	Positive	Negative	Positive
Galactose	1.0 g/dL	Negative	Positive	Negative	Positive
Gamma Globulin	0.5 g/dL	Negative	Positive	Negative	Positive
Glucose	2.0 g/dL	Negative	Positive	Negative	Positive
Hemoglobin	115 mg/dL	Negative	Positive	Negative	Positive
Human Serum Albumin	0.5 g/dL	Negative	Positive	Negative	Positive
Oxalic Acid	0.1 g/dL	Negative	Positive	Negative	Positive
Riboflavin	7.5 mg/dL	Negative	Positive	Negative	Positive
Sodium Azide	1% w/v	Negative	Positive	Negative	Positive
Sodium Chloride	6.0 g/dL	Negative	Positive	Negative	Positive
Sodium Fluoride	1% w/v	Negative	Positive	Negative	Positive
Urea	6.0 g/dL	Negative	Positive	Negative	Positive

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(viii) Specific Gravity and pH

Drug free urine pools with specific gravity values ranging from 1.002 to 1.035 and pH values ranging from 3.0 to 11.0 were prepared and spiked to final concentrations of 75 ng/mL, 125 ng/mL, 225 ng/mL and 375 ng/mL oxycodone. These samples were then evaluated in qualitative and semiquantitative modes. No positive or negative interference was observed.

(ix) Conclusion

The proposed Syva Emit® II Plus Oxycodone assay is substantially equivalent to the legally marketed predicate device based on intended use, principle and the performance characteristics above.