November 15, 2019

Immunalysis Corporation
Yang Yang
Regulatory Affairs Specialist II
829 Towne Center Drive
Pomona, CA 91767

Re: K190397
Trade/Device Name: Immunalysis Carisoprodol Metabolite / Meprobamate Urine HEIA
Regulation Number: 21 CFR 862.3590
Regulation Name: Meprobamate Test System
Regulatory Class: Class II
Product Code: QBK
Dated: October 3, 2019
Received: October 4, 2019

Dear Yang Yang:

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.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190397

Device Name
Immunalysis Carisoprodol Metabolite / Meprobamate Urine HEIA

Indications for Use *(Describe)*
The Immunalysis Carisoprodol Metabolite / Meprobamate Urine HEIA is a homogeneous enzyme immunoassay for the qualitative analysis of carisoprodol metabolite, Meprobamate, at a cutoff of 280 ng/mL in human urine. The assay is intended for use in laboratories with automated clinical chemistry analyzers. This in vitro diagnostic device is for prescription use only.

The Immunalysis Carisoprodol Metabolite / Meprobamate Urine HEIA 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 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: K190397

A. GENERAL INFORMATION

Applicant Name:	Immunalysis Corporation 829 Towne Center Drive Pomona, CA 91767 Establishment # 2020952
Company Contact:	Yang Yang Regulatory Affairs Specialist II Phone: (909) 451-6665 Email: yyang@immunalysis.com
Date Prepared:	November 13, 2019

B. DEVICE IDENTIFICATION

Trade or Proprietary Names:	Immunalysis Carisoprodol Metabolite / Meprobamate Urine HEIA
Common Name:	Carisoprodol Metabolite / Meprobamate Urine Enzyme Immunoassay

C. REGULATORY INFORMATION

Device Classification Name:	Meprobamate Test System
Product Codes:	QBK
Regulatory Class:	II
Classification Regulation:	21 CFR 862.3590, Meprobamate Test System
Panel:	Toxicology (91)
Predicate Device:	Lin-Zhi Carisoprodol Metabolite (Meprobamate) Enzyme Immunoassay, Meprobamate Drugs of Abuse Calibrators and Controls [DEN170010]

D. DEVICE DESCRIPTION

The Immunalysis Carisoprodol Metabolite / Meprobamate Urine HEIA is a sensitive *in vitro* diagnostic test intended for use in laboratories for the qualitative analysis of Meprobamate at a cutoff of 280 ng/mL in human urine with automated clinical chemistry analyzers.

Carisoprodol (N-isopropylmeprobamate, Soma, ingredient of Soma Compound, Somadril®) is a carbamate derivative first synthesized in 1959 and used clinically as a muscle relaxant and sedative. Carisoprodol is known to be metabolized to meprobamate and hydroxyl-meprobamate.

The assay is based on the competition of carisoprodol labeled enzyme glucose-6-phosphate

dehydrogenase (G6PDH) and the free Meprobamate in the urine sample for the fixed amount of sheep anti-carisoprodol antibody binding sites. In the absence of the free Meprobamate in the sample, the antibody binds the drug enzyme conjugate and enzyme activity is inhibited. This creates a dose response relationship between drug concentration in the urine and enzyme activity. The enzyme G6PDH activity is determined at 340 nm spectrophotometrically by the conversion of nicotinamide adenine dinucleotide (NAD) to NADH.

E. INTENDED USE

The Immunalysis Carisoprodol Metabolite / Meprobamate Urine HEIA is a homogenous enzyme immunoassay for the qualitative analysis of carisoprodol metabolite, Meprobamate, at a cutoff of 280 ng/mL in human urine. The assay is intended for use in laboratories with automated clinical chemistry analyzers. This *in vitro* diagnostic device is for prescription use only.

The Immunalysis Carisoprodol Metabolite / Meprobamate Urine HEIA 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 drug of abuse test result, particularly when preliminary positive results are used.

F. COMPARISON WITH PREDICATE

Attribute	**Predicate Device Lin-Zhi Carisoprodol Metabolite (Meprobamate) Enzyme Immunoassay [DEN170010]**	**Candidate Device Immunalysis Carisoprodol Metabolite / Meprobamate Urine HEIA**
Similarities		
Intended Use	For the qualitative and semi-quantitative determination of the presence of carisoprodol metabolite (meprobamate) in human urine with automated clinical chemistry analyzers.	For the qualitative analysis of carisoprodol metabolite, meprobamate, in human urine with automated clinical chemistry analyzers.
Test Principle	Homogeneous Enzyme Immunoassay	Same
User Environment	For use in laboratories	Same
Sample Matrix	Human Urine	Same
Mass Spectrometry Confirmation	Required for preliminary positive analytical results	Same
Reagent Storage	2-8°C until expiration date	Same
Assay Materials	2 analytical regents: Antibody/Substrate Reagent and Enzyme Labeled Conjugate	Same
Differences		
Assay Cutoff Level	100 ng/mL	280 ng/mL

Attribute	Predicate Device Lin-Zhi Carisoprodol Metabolite (Meprobamate) Enzyme Immunoassay [DEN170010]	Candidate Device Immunalysis Carisoprodol Metabolite / Meprobamate Urine HEIA
Antibody	Mouse monoclonal anti-meprobamate	Polyclonal sheep antibodies to carisoprodol
Calibrator	Meprobamate	Carisoprodol

G. PERFORMANCE CHARACTERISTICS

The following laboratory performance studies were performed to determine substantial equivalence of the Immunalysis Carisoprodol Metabolite / Meprobamate Urine HEIA to the predicate device. Assay performance was established using the Olympus AU400e analyzer.

1. Precision/Cutoff Characterization - Meprobamate

Precision/Cutoff Characterization study for meprobamate was performed for ten days using three product lots with two runs per day in replicates of four on drug free urine (N=80) spiked with meprobamate to concentrations of ±25%, ±50%, ±75%, and ±100% of the cutoff. The spiked concentrations were confirmed by Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS). The study verified that the cutoff serves as a boundary between a negative and positive interpretation of a qualitative result. Precision test results in qualitative mode are presented in **Table 9 - 11**.

Table 1. Meprobamate Precision - Lot#1

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
70	-75%	80	80 Negative
140	-50%	80	80 Negative
210	-25%	80	80 Negative
280	Cutoff	80	40 Neg/40 Pos
350	+25%	80	80 Positive
420	+50%	80	80 Positive
490	+75%	80	80 Positive
560	+100%	80	80 Positive

Table 2. Meprobamate Precision - Lot#2

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
70	-75%	80	80 Negative
140	-50%	80	80 Negative
210	-25%	80	80 Negative
280	Cutoff	80	38 Neg/42 Pos
350	+25%	80	80 Positive
420	+50%	80	80 Positive

Concentration (ng/mL)	% of cutoff	# of determinations	Result
490	+75%	80	80 Positive
560	+100%	80	80 Positive

Table 3. Meprobamate Precision - Lot#3

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
70	-75%	80	80 Negative
140	-50%	80	80 Negative
210	-25%	80	80 Negative
280	Cutoff	80	39 Neg/41 Pos
350	+25%	80	80 Positive
420	+50%	80	80 Positive
490	+75%	80	80 Positive
560	+100%	80	80 Positive

2. Specificity and Cross-Reactivity

Structurally and functionally similar compounds to meprobamate were spiked into drug free urine at levels that will yield a result that is equivalent to the cutoff. The study verified assay performance relative to the ability of the device to exclusively determine certain drugs in the qualitative mode. Cross-reactivity test results in qualitative mode are presented in **Table 4**.

Table 4. Cross-Reactivity – Qualitative

Compound	Compound Conc. (ng/mL)	Result	Cross-Reactivity (%)
Meprobamate	280	POS	100%
Carisoprodol	100	POS	280%
Buprenorphine	100,000	NEG	<0.1%
Codeine	100,000	NEG	<0.1%
Darunavir	200,000	NEG	N/D
Dihydrocodeine	100,000	NEG	<0.1%
Efavirenz	200,000	NEG	N/D
Felbamate	120,000	POS	0.2
Hydrocodone	100,000	NEG	<0.1%
Hydromorphone	100,000	NEG	<0.1%
Meperidine	100,000	NEG	<0.1%
Methocarbamol	200,000	NEG	N/D
Mitomycin C	200,000	NEG	N/D
Morphine	100,000	NEG	<0.1%
Morphine-3-glucuronide	100,000	NEG	<0.1%
Morphine-6-glucuronide	100,000	NEG	<0.1%

Compound	Compound Conc. (ng/mL)	Result	Cross-Reactivity (%)
Naloxone	100,000	NEG	<0.1%
Naltrexone	100,000	NEG	<0.1%
Neostigmine	200,000	NEG	N/D
Norbuprenorphine	100,000	NEG	<0.1%
Norcodeine	100,000	NEG	<0.1%
Normorphine	100,000	NEG	<0.1%
Oxycodone	100,000	NEG	<0.1%
Oxymorphone	100,000	NEG	<0.1%
Propoxyphene	100,000	NEG	<0.1%
Retigabine	200,000	NEG	N/D
Ritonavir	200,000	NEG	N/D
Rivastigmine	200,000	NEG	N/D
Tramadol	100,000	NEG	<0.1%
Trazadone	100,000	NEG	<0.1%
Venlafaxine	100,000	NEG	<0.1%
Zafirlukast	200,000	NEG	N/D

3. Interference – Meprobamate – Structurally Unrelated Compounds

Structurally unrelated compounds were evaluated in qualitative mode by spiking the potential interfering compound into drug-free negative urine containing a meprobamate concentration equivalent to ±25% of the assay cutoff. All potential interferents analyzed verified that assay performance is unaffected by externally ingested compounds. The levels of structurally unrelated compounds that did not interfere in the assay are presented in **Table 12**.

Table 5. Non-Interfering Structurally Unrelated Compounds to Meprobamate

Compound	Conc. Tested (ng/mL)
4-Bromo-2,5,Dimethoxyphenethylamine	100,000
Acetaminophen	500,000
Acetylsalicylic Acid	500,000
6-Acetylcodeine	100,000
Alphenal	100,000
6-Acetylmorphine	100,000
Alprazolam	100,000
7-Aminoclonazepam	50,000
7-Aminoflunitrazepam	100,000
7-Aminonitrazepam	100,000
Amitriptyline	100,000
Amobarbital	100,000
S-(+) Amphetamine	100,000
Aprobarbital	100,000

Compound	Conc. Tested (ng/mL)
Barbital	100,000
Benzoylecgonine	100,000
Benzylpiperazine	100,000
Bromazepam	100,000
Bupropion	100,000
Butabarbital	100,000
Butalbital	100,000
Caffeine	500,000
Cannabidiol	100,000
Cannabinol	100,000
Carbamazepine	100,000
Chlordiazepoxide	100,000
Chlorpromazine	100,000
cis-Tramadol	100,000
Clobazam	100,000
Clomipramine	100,000
Clonazepam	100,000
Clozapine	100,000
Cocaine	100,000
Cotinine	100,000
Cyclobenzaprine	100,000
Cyclopentobarbital	100,000
Demoxepam	100,000
Desakylflurazepam	100,000
Desipramine	100,000
Dextromethorphan	100,000
Diazepam	100,000
Digoxin	100,000
Diphenhydramine	500,000
Dehydronorketamine	50,000
Delta-9-THC	100,000
Doxepin	100,000
Doxylamine	100,000
Ecgonine	100,000
Ecgonine methyl ester	100,000
EDDP	100,000
EMDP	100,000
1R,2S(-)-Ephedrine	100,000
1S,2R(+)-Ephedrine	100,000
Ethyl glucuronide	100,000

Compound	Conc. Tested (ng/mL)
Ethylmorphine	100,000
Fenfluramine	100,000
Fentanyl	100,000
Flunitrazepam	100,000
Fluoxetine	100,000
Flurazepam	100,000
Haloperidol	100,000
Heroin	100,000
Hexobarbital	100,000
11-hydroxy-delta-9-THC	100,000
Ibuprofen	500,000
Imipramine	100,000
Ketamine	100,000
Labetalol	100,000
Lamotrigine	100,000
Levorphanol tartrate	100,000
Lidocaine	100,000
Lorazepam	100,000
Lorazepam Glucuronide	50,000
Lormetazepam	100,000
LSD	100,000
Maprotiline	100,000
MDA	100,000
MDEA	100,000
MDMA	100,000
S(+)-Methamphetamine	100,000
Methadone	500,000
Methaqualone	100,000
Methoxetamine	100,000
Methylone	100,000
Methylphenidate	100,000
Midazolam	100,000
N-desmethyl tapentadol	100,000
N-desmethyl venlafaxine	100,000
Nalorphine	100,000
Naproxen	100,000
Nitrazepam	100,000
11-nor-9 carboxy THC	100,000
Nordiazepam	100,000
Norketamine	100,000

Compound	Conc. Tested (ng/mL)
Norpropoxyphene	100,000
Norpseudoephedrine	100,000
Nortriptyline	100,000
O-desmethyl tramadol	100,000
O-desmethyl venlafaxine	100,000
Olanzapine	100,000
Oxazepam	100,000
PCP	100,000
Pentobarbital	100,000
Pentazocine	100,000
Phenazepam	100,000
Phenobarbital	100,000
Phentermine	100,000
Phenylephedrine	100,000
Phenytoin	100,000
Phenylpropanolamine	100,000
PMA	100,000
Prazepam	100,000
Propranolol	100,000
Protriptyline	100,000
R,R(-)-Pseudoephedrine	100,000
S,S(+)-Pseudoephedrine	100,000
Ritalinic Acid	100,000
Salicylic Acid	100,000
Secobarbital	100,000
Sertraline	100,000
Sufentanil Citrate	50,000
Talbutal	100,000
Tapentadol	100,000
Temazepam	100,000
Theophylline	100,000
Thiopental	100,000
Thioridazine	100,000
Triazolam	100,000
Trifluoromethylphenyl-piperazine	100,000
Trimipramine	100,000
Verapamil	100,000
Zolpidem Tartrate	100,000

4. Interference - Endogenous Compounds and Urine Preservatives

Endogenous compounds and urine preservatives were evaluated in qualitative mode by spiking the potential interferent into drug free urine containing meprobamate concentration equivalent to ±25% of the assay cutoff. Due to the interference of boric acid observed at ±25% of the cutoff, potential interference was also evaluated at ±50% of the cutoff. Other than boric acid, assay performance is unaffected by all the other internally existing physiological conditions or urine preservatives tested. Compounds tested that did not interfere in the assay are presented in **Table 13**. Boric acid interference test results in qualitative mode are presented in **Table 14**.

Table 6. Non-Interfering Endogenous Compounds and Urine Preservatives

Compound	Conc. Tested (ng/mL)
Acetone	1.0 g/dL
Ascorbic Acid	1.5 g/dL
Bilirubin	0.002 g/dL
Creatinine	0.5 g/dL
Ethanol	1.0 g/dL
Galactose	0.01 g/dL
γ-Globulin	0.5 g/dL
Glucose	2.0 g/dL
Hemoglobulin	0.300 g/dL
Human Serum Albumin	0.5 g/dL
Oxalic Acid	0.1 g/dL
Riboflavin	0.0075 g/dL
Sodium Azide	1% w/v
Sodium Chloride	6.0 g/dL
Sodium Fluoride	1% w/v
Urea	6.0 g/dL

Table 7. Boric Acid Interference

Compound	Concentration Tested	Qualitative Result	
		-50% Cutoff (140 ng/mL)	+50% Cutoff (420 ng/mL)
Boric Acid	1% w/v	Negative	Negative

5. Interference – pH

To evaluate potential interference from the effect of urine pH, device performance in the qualitative mode was tested at pH values 3.0, 7.0 and 11.0. All test samples were prepared in drug-free urine containing meprobamate at the concentration equivalent to ±25% of the carisoprodol assay cutoff. No positive or negative interference was observed at urine pH values 3.0, 7.0 and 11.0 for each test mode.

6. Interference - Specific Gravity

To evaluate potential interference from the specific gravity of urine, device performance in the

qualitative mode was tested at physiologically relevant urine specific gravity values 1.000, 1.015 and 1.030. All test samples were prepared in drug free urine containing meprobamate at the concentration equivalent to ±25% of the carisoprodol assay cutoff. No positive or negative interference was observed at urine specific gravity values 1.000, 1.015 and 1.030 for each test mode.

7. Calibration Duration

Drug free negative urine spiked with carisoprodol at ±25% of the cutoff were tested in qualitative mode at time points up to 14 days. At the initial time point, a two-point calibration curve was established. This calibration was used through the duration of this study. The test results met acceptance criteria at each time point. The recommended frequency of calibration is 14 days.

8. Specimen Stability (Urine)

De-identified, unaltered clinical urine samples containing carisoprodol and/or meprobamate obtained from clinical testing were tested by LC-MS/MS at each time point at 22°C - 30°C and at 2°C - 8°C. Test results indicated that urine samples containing carisoprodol and/or meprobamate are stable for up to 7 days stored at ambient temperature up to 30°C and up to 6 months stored at 2°C - 8°C.

9. Urine Elimination Study

The ten subjects were self-reported single dose users of either 250 mg or 350 mg of carisoprodol and have taken the single dose of carisoprodol within 48 hours of enrollment and did not take carisoprodol for 96 hours after enrollment. The subjects were instructed to collect his/her first urine at the time of enrollment and every 12-24 hours from time of enrollment. The collected samples were screened with Immunalysis Carisoprodol Metabolite / Meprobamate Urine HEIA in qualitative mode in singlicate. Carisoprodol and Meprobamate mass spectrometry analysis was performed for all samples. The earliest time post ingestion of drug that the carisoprodol or meprobamate in the urine specimen decreased below cutoff level is 45.5 hours.

10. Method Comparison

A total of one hundred and sixty seven (167) de-identified, unaltered leftover clinical urine samples obtained from clinical testing laboratories were analyzed by the Immunalysis Carisoprodol Metabolite / Meprobamate Urine HEIA and by LC-MS/MS. The cutoff of 280 ng/mL of meprobamate was used to distinguish positive results from negative results for LC-MS/MS. Fifty-five (55) specimens showed negative results by both methods, and one hundred and seven (107) specimens showed positive results by both methods. Results are shown in **Table 8**. The five false positive samples (indicated by an asterisk) each contained carisoprodol and are not a cause for clinical concern (see **Table 9**). The instruments used were an Olympus AU 400e and an Agilent 6430 Liquid Chromatography-Tandem Mass Spectrometry.

Table 8. Method Comparison

Immunalysis Meprobamate Urine HEIA Result	LC-MS/MS Total Meprobamate Concentration				Agreement (%)
	< 140 ng/mL (less than -50% cutoff)	140-279 ng/mL (between -50% cutoff and cutoff)	280-420 ng/mL (between cutoff and +50% cutoff)	> 420 ng/mL (greater than +50% cutoff)	
Positive	3	2	3	104	100% (107/107)
Negative	51	4	0	0	92% (55/60)

Table 9 Discrepant Samples

Qualitative Result	Meprobamate (ng/mL)	Carisoprodol (ng/mL)
POS	0	147
POS	0	148
POS	0	750
POS	201	35,156
POS	230	120,593

H. CONCLUSION

The information provided in this pre-market notification demonstrates that the Immunalysis Carisoprodol Metabolite / Meprobamate Urine HEIA is substantially equivalent to the legally marketed predicate device for its intended use.