K131168

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510(k) SUMMARY

JAN 17 2014

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

A. Contact Information

1. Manufacturer:	Immunalysis Corporation
2. Contact Name:	Joseph Ginete
3. Contact Title:	Regulatory Affairs Specialist
4. Address:	829 Towne Center Drive Pomona, CA 91767
5. Phone:	(909) 482-0840
6. Fax:	(909) 482-0850
7. Email:	jginete@immunalysis.com
8. Summary prepared on:	December 20, 2013

B. Device Information

1. Trade Name:	Immunalysis Oxycodone Urine Enzyme Immunoassay Immunalysis Oxycodone Urine Controls Immunalysis Oxycodone Urine Calibrators
2. Common Name:	Immunalysis Oxycodone Urine Enzyme Immunoassay Immunalysis Oxycodone Urine Controls Immunalysis Oxycodone Urine Calibrators
3. Device Classification:	II
4. Regulation Number:	CFR 862.3650 Opiate Test System CFR 862.3200 Clinical Toxicology Calibrator CFR 862.3280 Clinical Toxicology Control Materials
5. Panel:	Toxicology(91)
6. Product Code:	DJG DLJ LAS

C. Legally Marketed Device to Which We are Claiming Equivalence (807.92(A)(3))

1. Predicate Device:	DRI Oxycodone Assay DRI Oxycodone Controls DRI Oxycodone Calibrators
2. Predicate Company:	Microgenics
3. Predicate K Number:	K040411

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D. Device Description

The assay consists of antibody/ substrate reagent and enzyme conjugate reagent. The antibody/ substrate reagent includes recombinant monoclonal antibodies to Oxycodone, glucose-6-phosphate (G6P) and nicotinamide adenine dinucleotide (NAD) in Tris buffer with Sodium Azide as a preservative. The enzyme conjugate reagent includes oxycodone derivative labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with Sodium Azide as a preservative. Calibrators and controls are sold separately. Reagents are liquid, ready to use

The oxycodone calibrator and controls consists of a single calibrator at 100ng/mL or 300ng/mL, a control set containing a LOW control (75ng/mL or 225ng/mL) and a HIGH control (125ng/mL or 375ng/mL) and a calibrator set containing a negative calibrator, a Level 1 calibrator at 100ng/mL, a Level 2 calibrator at 300ng/mL, a Level 3 calibrator at 500ng/mL and a Level 4 calibrator at 1000ng/mL.

E. Intended Use

Immunalysis Oxycodone Urine Enzyme Immunoassay:

The Immunalysis Oxycodone Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a dual cutoff of 100ng/mL and 300ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of Oxycodone in human urine with automated clinical chemistry analyzers. This assay is calibrated against Oxycodone. This in-vitro device is for prescription use only.

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 GC-MS or permitting laboratories to establish quality control procedures.

The Immunalysis Oxycodone Urine Enzyme Immunoassay Kit 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 / Mass Spectroscopy (LC/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.

Immunalysis Oxycodone Urine Controls:

The Immunalysis Oxycodone Urine Controls are used as control materials in the Immunalysis Oxycodone Urine Enzyme Immunoassay.

Immunalysis Oxycodone Urine Calibrators:

The Immunalysis Oxycodone Urine Calibrators are used as calibrators in the Immunalysis Oxycodone Urine Enzyme Immunoassay for the qualitative and semi-quantitative determination of Oxycodone in urine on automated clinical chemistry analyzers.

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F. Comparison of the new device with the predicate device

Item	Predicate Device (K040411)	Test Device
Type of Product	Analytical Reagents	Analytical Reagents
Measured Analytes	Oxycodone	Oxycodone
Test Matrix	Urine	Urine
Cutoff Levels	100ng/mL and 300ng/mL of Oxycodone	100ng/mL and 300ng/mL of Oxycodone
Test System	Homogenous Enzyme Immunoassay	Homogenous Enzyme Immunoassay
Materials	Antibody/ Substrate Reagents and Enzyme Labeled Conjugate	Antibody/ Substrate Reagents and Enzyme Labeled Conjugate
Mass Spectroscopy Confirmation	Required for preliminary positive analytical results	Required for preliminary positive analytical results
Antibody	Mouse monoclonal anti-oxycodone derivative	Recombinant FAB Antibody to Oxycodone
Storage	2 – 8°C until expiration date	2 – 8°C until expiration date
Calibrator Form	Liquid	Liquid
Calibrator Levels	One (1) Level (100ng/mL or 300ng/mL)	One (1) Level (100ng/mL or 300ng/mL)
Control Set Levels	Two (2) Levels (75ng/mL and 125ng/mL or 225ng/mL and 375 ng/mL)	Two (2) Levels (75ng/mL and 125ng/mL or 225ng/mL and 375 ng/mL)
Calibrator Set Levels	Five (5) Levels (0, 100, 300, 500 and 1000 ng/mL)	Five (5) Levels (0, 100, 300, 500 and 1000 ng/mL)

G. The following laboratory performance studies were performed to determine substantial equivalence of the Immunalysis Oxycodone Urine Enzyme Immunoassay to the predicate

1. Precision/ Cutoff Characterization
2. Specificity and Cross-Reactivity
3. Interference
4. Linearity/ Recovery
5. Method Comparison
6. Stability

H. Conclusion

The information provided in this pre-market notification demonstrates that the Immunalysis Oxycodone Urine Enzyme Immunoassay is substantially equivalent to the legally marketed predicate device for its general intended use. The information supplied in this pre-market notification provides reasonable assurance that the Immunalysis Oxycodone Urine Enzyme Immunoassay is safe and effective for its intended use

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

January 17, 2014

IMMUNALYSIS CORPORATION
JOSEPH GINETE
REGULATORY AFFAIRS SPECIALIST
829 TOWNE CENTER DR.
POMONA CA 91767

Re: K131168
Trade/Device Name: Immunalysis Oxycodone Enzyme Immunoassay
Immunalysis Oxycodone Urine Controls
Immunalysis Oxycodone Urine Calibrators
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG, DLJ, LAS
Dated: December 20, 2013
Received: December 26, 2013

Dear Mr. Ginete:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131168

Device Name
Immunalysis Oxycodone Urine Enzyme Immunoassay, Immunalysis Oxycodone Urine Controls and Immunalysis Oxycodone Urine Calibrators

Indications for Use *(Describe)*
Immunalysis Oxycodone Urine Enzyme Immunoassay:
The Immunalysis Oxycodone Urine Enzyme ImmunoaAssay is a homogeneous enzyme immunoassay with a dual cutoff of 100ng/mL and 300ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of Oxycodone in human urine with automated clinical chemistry analyzers. This assay is calibrated against Oxycodone. This in-vitro device is for prescription use only.
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 GC-MS or permitting laboratories to establish quality control procedures.
The Immunalysis Oxycodone Urine Enzyme Immunoassay Kit 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 / Mass Spectroscopy (LC/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.

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Immunalysis Oxycodone Urine Calibrators:
The Immunalysis Oxycodone Urine Calibrators are used as calibrators in the Immunalysis Oxycodone Urine Enzyme Immunoassay for the qualitative and semi-quantitative determination of Oxycodone in urine on automated clinical chemistry analyzers.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Avis T. Danishefsky -S