K110298

510(k) Summary of Safety and Effectiveness

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

JUL 15 2011

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter Name, Address, and Contact

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Contact: Bernice Lin, Ph.D.
VP Operations

Device Name and Classification

Classification Name:	Enzyme Immunoassay, Opiate Class II, DJG (91 Toxicology), 21 CFR 862.3650
Common Name:	Homogeneous Opiate Enzyme Immunoassay
Proprietary Name:	Opiate Enzyme Immunoassay,

Legally Marketed Predicate Device(s)

The Opiate Enzyme Immunoassay (EIA) is substantially equivalent to the Lin-Zhi International, Inc. Opiate Enzyme Immunoassay for Hitachi 717 Systems (k020368) manufactured by Lin-Zhi International, Inc. The Opiate Enzyme Immunoassay is identical or similar to its predicate in terms of intended use, method principle, device components, and clinical performance.

Device Description (Assay Principle)

The Opiate Enzyme Immunoassay is a homogeneous enzyme immunoassay ready-to-use liquid reagent. The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for a fixed amount of antibody in the reagent.

Enzyme activity decreases upon binding to the antibody, and the drug concentration in the sample is measured in terms of enzyme activity. In the absence of drug in the sample, morphine-labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. On the other hand, when free drug is present in the sample, antibody would bind to free drug, the unbound morphine-labeled G6PDH then exhibits its maximal enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that can be measured spectrophotometrically at 340 nm.

Intended Use

The Opiate Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of opiates in human urine, at a cutoff value of 300 ng/mL. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

The Opiate Drugs of Abuse (DAU) Calibrators (from k020769) are for use as calibrators in the qualitative and semi-quantitative calibration of the Opiate Enzyme Immunoassay.

The Opiate Drugs of Abuse (DAU) Controls (from k020769) are for use as assayed quality control materials to monitor the precision of the Opiate Enzyme Immunoassay.

The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method). Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

Comparison to Predicate Device

The Opiate Enzyme Immunoassay is substantially equivalent to the Lin-Zhi International, Inc. Opiate Enzyme Immunoassay for Hitachi 717 Systems cleared by the FDA under the premarket notification k020368 for its stated intended use.

The following table compares the Opiate Enzyme Immunoassay with the predicate device.

Device Characteristics	**Subject Device** Opiate Enzyme Immunoassay	**Predicate Device (k020368)** Opiate Enzyme Immunoassay
Intended Use	The Opiate Enzyme Immunoassay, when used in conjunction with Hitachi 717 automated clinical system analyzers, is intended for the qualitative and semi-quantitative determination of opiates in human urine, at a cutoff value of 300 ng/mL. The assay is designed for professional use with a number of automated clinical chemistry analyzers. ***This assay provides a rapid screening procedure for determining the presence of Opiates in urine. The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.***	The Opiate Enzyme Immunoassay, when used in conjunction with Hitachi 717 automated clinical system analyzers, is intended for the qualitative and semi-quantitative determination of opiates in human urine, at a cutoff value of 300 ng/mL. The assay is designed for professional use with a number of automated clinical chemistry analyzers. ***This assay provides a rapid screening procedure for determining the presence of Opiates in urine. The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.***
Analyte	Opiates	Opiates
Cutoff	300 ng/ml	300 ng/mL
Matrix	Urine	Urine
Calibrators Level	5 Levels (0, 150, 300, 600, 1000 ng/mL)	5 Levels (0, 150, 300, 600, 1000 ng/mL)
Controls Level	2 Levels (225 ng/mL, 375 ng/mL)	2 Levels (225 ng/mL, 375 ng/mL)
Storage	2-8 °C until expiration date	2-8 °C until expiration date

Performance Characteristics Summary:

Hitachi 717 Analyzer

Precision:

Precision: Semi-Quantitative, ng/mL

N=88 (ng/mL)	Within Run			Total Precision		
	Mean	SD	% CV	Mean	SD	% CV
0 ng/mL	0.0	0.0	#DIV/0!	0.0	0.0	#DIV/0!
75 ng/mL	84.0	3.5	4.2%	84.0	4.5	5.4%
150 ng/mL	148.4	3.7	2.5%	148.4	4.2	2.8%
225 ng/mL	228.2	5.3	2.3%	228.2	6.4	2.8%
300 ng/mL	297.5	6.3	2.1%	297.5	7.3	2.4%
375 ng/mL	370.4	7.6	2.0%	370.4	8.2	2.2%
450 ng/mL	453.3	9.8	2.2%	453.3	10.1	2.2%
525 ng/mL	529.0	11.5	2.2%	529.0	12.7	2.4%
600 ng/mL	600.8	16.2	2.7%	600.8	17.5	2.9%

Semi-Quantitative Precision Analysis Summary: Qualitative Results

N=88 (ng/mL)	Within Run		Total Precision	
	Mean	Qualitative Response	Mean	Qualitative Response
0 ng/mL	0.0	-	0.0	-
75 ng/mL	84.0	-	84.0	-
150 ng/mL	148.4	-	148.4	-
225 ng/mL	228.2	-	228.2	-
300 ng/mL	297.5	-	297.5	-
375 ng/mL	370.4	+	370.4	+
450 ng/mL	453.3	+	453.3	+
525 ng/mL	529.0	+	529.0	+
600 ng/mL	600.8	+	600.8	+

Semi-Quantitative Positive/Negative Results:

300 ng/mL Cutoff Result:		Within Run		Total Precision	
Sample Concentration	% of Cutoff	Number of Determination	Immunoassay Result	Number of Determination	Immunoassay Result
0 ng/mL	-100.0%	22	22 Negative	88	88 Negative
75 ng/mL	-75.0%	22	22 Negative	88	88 Negative
150 ng/mL	-50.0%	22	22 Negative	88	88 Negative
225 ng/mL	-25.0%	22	22 Negative	88	88 Negative
300 ng/mL	100.0%	22	6 Pos/16 Neg	88	27 Pos/61 Neg
375 ng/mL	+25.0%	22	22 Positive	88	88 Positive
450 ng/mL	+50.0%	22	22 Positive	88	88 Positive
525 ng/mL	+75.0%	22	22 Positive	88	88 Positive
600 ng/mL	+100.0%	22	22 Positive	88	88 Positive

Precision: Qualitative, mA/min

N=88 (mA/min)	Within Run			Total Precision		
	Mean	SD	% CV	Mean	SD	% CV
0 ng/mL	261.0	2.1	0.8%	261.0	2.4	0.9%
75 ng/mL	310.4	1.8	0.6%	310.4	2.4	0.8%
150 ng/mL	345.6	2.1	0.6%	345.6	3.2	0.9%
225 ng/mL	383.6	2.4	0.6%	383.6	3.7	1.0%
300 ng/mL	410.9	2.3	0.6%	410.9	3.7	0.9%
375 ng/mL	432.1	2.5	0.6%	432.1	3.6	0.8%
450 ng/mL	454.3	2.8	0.6%	454.3	4.0	0.9%
525 ng/mL	471.0	2.5	0.5%	471.0	4.4	0.9%
600 ng/mL	482.6	2.5	0.5%	482.6	3.6	0.8%

Qualitative Positive/Negative Results:

300 ng/mL Cutoff Result:		Within Run		Total Precision	
Sample Concentration	% of Cutoff	Number of Determination	Immunoassay Result	Number of Determination	Immunoassay Result
0 ng/mL	-100.0%	22	22 Negative	88	88 Negative
75 ng/mL	-75.0%	22	22 Negative	88	88 Negative
150 ng/mL	-50.0%	22	22 Negative	88	88 Negative
225 ng/mL	-25.0%	22	22 Negative	88	88 Negative
300 ng/mL	100.0%	22	16 Pos/6 Neg	88	51Pos/37 Neg
375 ng/mL	+25.0%	22	22 Positive	88	88 Positive
450 ng/mL	+50.0%	22	22 Positive	88	88 Positive
525 ng/mL	+75.0%	22	22 Positive	88	88 Positive
600 ng/mL	+100.0%	22	22 Positive	88	88 Positive

Limit of Detection:

The lowest concentration that can be differentiated from the negative urine with 95% confidence is determined as 20 ng/mL.

Linearity:

Hitachi 717 Instrument: 0 - 1000 ng/mL

When comparing the result (y) and target (x) value, using the least squares regression technique, the regression equation and correlation are as follow:

$y = 1.0619x - 2.3861$, $r^2 = 0.9976$

Method Comparison: Clinical Samples

From a total of One-hundred-thirty (130) clinical unaltered samples:

Semi-Quantitative Results: 98.3 % agreement with positive, 95.9 % agreement with negative samples

Qualitative Results: 98.3 % agreement with positive, 94.5 % agreement with negative samples

Endogenous Compound Interference, Specific Gravity, & Specificity - Cross-Reactivity:

No significant undesired cross reactants or endogenous substance interference was observed. See product insert for list of compounds tested.

Summary:

The information provided in this pre-market notification demonstrates that the LZI Opiate Enzyme Immunoassay is substantially equivalent to the legally marketed predicate device for its general intended use. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available predicate device as confirmed by gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS), an independent analytical method. The information supplied in this pre-market notification provides reasonable assurance that the LZI Opiate Enzyme Immunoassay is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Lin-Zhi International, Inc.
c/o Dr. Bernice Lin
VP Operations
670 Almanor Avenue
Sunnyvale, CA 94085

JUL 15 2011

Re: k110298
Trade name: Opiate Enzyme Immunoassay
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG
Dated: June 17, 2011
Received: June 20, 2011

Dear Dr. Lin:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Premarket Notification

Indications for Use Statement

510(k) Number (if known): k110298

Device Name: Opiate Enzyme Immunoassay

Indications for Use:

The Opiate Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of opiates in human urine, at a cutoff value of 300 ng/mL when calibrated against morphine. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

The semi-quantitative mode is for purposes of (1) enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GCMS or (2) permitting laboratories to establish quality control procedures."

The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method). Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

Prescription Use √ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
(Per 21 CFR 801.109)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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