

K120761

MAY - 8 2012

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.

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

Drug Specific Calibrators,
Class II, DLJ (91 Toxicology),
21 CFR 862.3200

Drug Specific Controls,
Class I, LAS (91 Toxicology),
21 CFR 862.3280

Common Name: Homogeneous Opiate 2000 Enzyme Immunoassay
Proprietary Name: LZI Opiate 2000 Enzyme Immunoassay,
LZI Opiate 2000 Drugs of Abuse (DAU) Calibrators
LZI Opiate 2000 Drugs of Abuse (DAU) Controls

Legally Marketed Predicate Device(s)

The LZI Opiate 2000 Enzyme Immunoassay (EIA) at a cutoff of 2000 ng/mL is substantially equivalent to the LZI Opiate Enzyme Immunoassay and Opiate Calibrators and Controls (k020638 & k020769) manufactured by Lin-Zhi International, Inc with a cutoff of 300 ng/mL. The LZI Opiate 2000 Enzyme Immunoassay is identical or similar to its predicate in terms of intended use, method principle, device components, and clinical performance.

Device Description

The LZI Opiate 2000 assay is a homogeneous enzyme immunoassay with ready-to-use liquid reagents. 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.

The LZI Opiate 2000 Enzyme Immunoassay is a kit comprised of two reagents, an R₁ and R₂, which are bottled separately but sold together within the kit.

The R₁ solution contains mouse monoclonal anti-morphine antibody, glucose-6-phosphate (G6P) nicotinamide adenine dinucleotide (NAD), stabilizers, and sodium azide (0.09%) as a preservative. The R₂ solution contains glucose-6-phosphate dehydrogenase (G6PDH) labeled with morphine in buffer with sodium azide (0.09%) as preservative.

The LZI Opiate 2000 Enzyme Immunoassay calibrators and controls designated for use at the 2000 ng/mL cutoff contain 0, 1000, 1500, 2000, 2500, 4000, and 6000 ng/mL of morphine in human urine with sodium azide (0.09%) as preservative. These five calibrators and two controls are sold as individual bottles.

Intended Use

The LZI Opiate 2000 Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of morphine in human urine at a cutoff value of 2000 ng/mL. 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 and LCMS or (2) permitting laboratories to establish quality control procedures.

The LZI Opiate 2000 Drugs of Abuse (DAU) Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Opiate 2000 Enzyme Immunoassay at a cutoff value of 2000 ng/mL.

The LZI Opiate 2000 Drugs of Abuse (DAU) Controls are for use as assayed quality control materials to monitor the precision of the LZI Opiate 2000 Enzyme Immunoassay at a cutoff value of 2000 ng/mL.

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 Lin-Zhi International, Inc. LZI Opiate 2000 Enzyme Immunoassay used at the 2000 ng/mL cutoff is substantially equivalent to the Lin-Zhi International, Inc. Opiate Enzyme Immunoassay, Calibrators and Controls for Hitachi 717 Systems cleared by the FDA under the premarket notification k020638 & k020769 for its stated intended use.

The following table compares LZI's Opiate 2000 Enzyme Immunoassay at the 2000 ng/mL cutoff with the predicate device.

| Device Characteristics | Subject Device LZI Opiate 2000 Enzyme Immunoassay, Calibrators and Controls | Predicate Device (k020638 & k020769) LZI Opiate Enzyme Immunoassay, Calibrators and Controls |
|-------------------------------|--|---|
| Intended Use | <p>The LZI Opiate 2000 Enzyme Immunoassay, when used in conjunction with Hitachi 717 automated clinical system analyzers, is intended for the qualitative and semi-quantitative determination of morphine in human urine at a cutoff value of 2000 ng/mL. The assay is designed for professional use with a number of automated clinical chemistry analyzers.</p> <p><i>This assay provides a rapid screening procedure for determining the presence of morphine 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.</i></p> | <p>The Opiate Enzyme Immunoassay from Lin-Zhi International, Inc., when used in conjunction with Hitachi 717 automated clinical system analyzers, is intended for the qualitative and semi-quantitative determination of morphine 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.</p> <p><i>This assay provides a rapid screening procedure for determining the presence of morphine 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.</i></p> |
| Analyte | morphine | morphine |
| Cutoff | 2000 ng/ml | 300 ng/mL |
| Matrix | Urine | Urine |
| Calibrators Level | 5 Levels (0, 1000, 2000, 4000, 6000 ng/mL) | 5 Levels (0, 150, 300, 600, 1000 ng/mL) |
| Controls Level | 2 Levels (1500 ng/mL, 2500 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 | 64.9 | 21.37 | 36.6% | 64.9 | 25.7 | 39.6% |
| 500 ng/mL | 448.9 | 18.11 | 4.1% | 448.9 | 22.1 | 4.9% |
| 1000 ng/mL | 1014.4 | 24.22 | 2.4% | 1014.4 | 24.8 | 2.4% |
| 1500 ng/mL | 1559.8 | 20.07 | 1.3% | 1559.8 | 22.6 | 1.4% |
| 2000 ng/mL | 2018.4 | 32.22 | 1.6% | 2018.4 | 37.6 | 1.9% |
| 2500 ng/mL | 2492.3 | 46.4 | 1.9% | 2492.3 | 47.0 | 1.9% |
| 3000 ng/mL | 3065.5 | 87.91 | 2.9% | 3065.5 | 90.1 | 2.9% |
| 3500 ng/mL | 3620.0 | 64.06 | 1.8% | 3620.0 | 71.4 | 2.0% |
| 4000 ng/mL | 4013.2 | 83.96 | 2.1% | 4013.2 | 96.9 | 2.4% |

Semi-Quantitative Precision Analysis Summary: Qualitative Results

| N=88 (ng/mL) | Within Run | | Total Precision | |
|-----------------|------------|----------------------|-----------------|----------------------|
| | Mean | Qualitative Response | Mean | Qualitative Response |
| 0 ng/mL | 64.9 | - | 64.9 | - |
| 500 ng/mL | 448.9 | - | 448.9 | - |
| 1000 ng/mL | 1014.4 | - | 1014.4 | - |
| 1500 ng/mL | 1559.8 | - | 1559.8 | - |
| 2000 ng/mL | 2018.4 | + | 2018.4 | + |
| 2500 ng/mL | 2492.3 | + | 2492.3 | + |
| 3000 ng/mL | 3065.5 | + | 3065.5 | + |
| 3500 ng/mL | 3620.0 | + | 3620.0 | + |
| 4000 ng/mL | 4013.2 | + | 4013.2 | + |

Semi-Quantitative Positive/Negative Results:

| 2000 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 |
| 500 ng/mL | -75.0% | 22 | 22 Negative | 88 | 88 Negative |
| 1000 ng/mL | -50.0% | 22 | 22 Negative | 88 | 88 Negative |
| 1500 ng/mL | -25.0% | 22 | 22 Negative | 88 | 88 Negative |
| 2000 ng/mL | 0% | 22 | 18 Pos/ 4 Neg | 88 | 59 Pos/ 29 Neg |
| 2500 ng/mL | +25.0% | 22 | 22 Positive | 88 | 88 Positive |
| 3000 ng/mL | +50.0% | 22 | 22 Positive | 88 | 88 Positive |
| 3500 ng/mL | +75.0% | 22 | 22 Positive | 88 | 88 Positive |
| 4000 ng/mL | +100.0% | 22 | 22 Positive | 88 | 88 Positive |

Performance Characteristics Summary: (continued)

Hitachi 717 Analyzer

Precision: Qualitative, mA/min

| N=88 (mA/min) | Within Run | | | Total Precision | | |
|------------------|------------|------|------|-----------------|-----|------|
| | Mean | SD | % CV | Mean | SD | % CV |
| 0 ng/mL | 229.2 | 1.67 | 0.7% | 229.2 | 1.9 | 0.8% |
| 500 ng/mL | 271.2 | 1.74 | 0.6% | 271.2 | 2.2 | 0.8% |
| 1000 ng/mL | 335.9 | 1.48 | 0.4% | 335.9 | 2.7 | 0.8% |
| 1500 ng/mL | 384.7 | 1.68 | 0.4% | 384.7 | 2.8 | 0.7% |
| 2000 ng/mL | 414.5 | 2.70 | 0.7% | 414.5 | 3.5 | 0.9% |
| 2500 ng/mL | 441.9 | 1.9 | 0.4% | 441.9 | 3.1 | 0.7% |
| 3000 ng/mL | 461.9 | 3.36 | 0.7% | 461.9 | 4.2 | 0.9% |
| 3500 ng/mL | 478.6 | 2.97 | 0.6% | 478.6 | 3.5 | 0.7% |
| 4000 ng/mL | 489.4 | 2.24 | 0.5% | 489.4 | 2.9 | 0.6% |

Qualitative Positive/Negative Results:

| 2000 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 |
| 500 ng/mL | -75.0% | 22 | 22 Negative | 88 | 88 Negative |
| 1000 ng/mL | -50.0% | 22 | 22 Negative | 88 | 88 Negative |
| 1500 ng/mL | -25.0% | 22 | 22 Negative | 88 | 88 Negative |
| 2000 ng/mL | 0% | 22 | 9 Pos/ 13 Neg | 88 | 33 Pos/ 55 Neg |
| 2500 ng/mL | +25.0% | 22 | 22 Positive | 88 | 88 Positive |
| 3000 ng/mL | +50.0% | 22 | 22 Positive | 88 | 88 Positive |
| 3500 ng/mL | +75.0% | 22 | 22 Positive | 88 | 88 Positive |
| 4000 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 200 ng/mL.

Linearity:

Hitachi 717 Instrument: 0 - 6000 ng/mL

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

$$y = 1.078x - 85.072, r^2 = 0.993$$

Method Comparison - Clinical Samples:

From a total of one-hundred fifty (150) clinical unaltered samples

Semi-Quantitative Data:

96.49% agreement with positive,

93.55% agreement with negative samples

Qualitative Data:

96.49% agreement with positive,

96.77% agreement with negative samples

Performance Characteristics Summary: (continued)

Hitachi 717 Analyzer

Endogenous Compound Interference & Specificity & Cross-Reactivity:

No significant undesired cross-reactants or endogenous substance interference was observed.

Summary:

The information provided in this pre-market notification demonstrates that the LZI Opiate 2000 Enzyme Immunoassay at a cutoff value of 2000 ng/mL 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 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 2000 Enzyme Immunoassay at a cutoff value of 2000 ng/mL is safe and effective for its stated intended use.



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Lin-Zhi International, Inc.
c/o Bernice Lin, Ph.D.
Vice President, Operations
670 Almanor Ave
Sunnyvale, CA 94085

MAY - 8 2012

Re: k120761

Trade/Device Name: LZI Opiate 2000 Enzyme Immunoassay, LZI Opiate 2000 Enzyme Calibrators and
LZI Opiate 2000 Enzyme Controls

Regulation Number: 21CFR 862.3650

Regulation Name: Opiate Test System

Regulatory Class: Class II

Product Code: DJG, DLJ and LAS

Dated: April 26, 2012

Received: April 27, 2012

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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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 H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
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): _____

**Device Name: LZI Opiate 2000 Enzyme Immunoassay
LZI Opiate 2000 Calibrators and Controls**

Indications for Use:

The LZI Opiate 2000 Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of morphine in human urine at the cutoff value of 2000 ng/mL. 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 and LCMS or (2) permitting laboratories to establish quality control procedures.

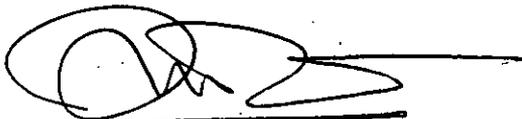
The LZI Opiate 2000 Drugs of Abuse (DAU) Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Opiate 2000 Enzyme Immunoassay at a cutoff value of 2000 ng/mL.

The LZI Opiate 2000 Drugs of Abuse (DAU) Controls are for use as assayed quality control materials to monitor the precision of the LZI Opiate 2000 Enzyme Immunoassay at a cutoff value of 2000 ng/mL.

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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

510(k) K120761