

K13165d

MAR 2 1 2014

## 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.*

### Preparation Date

March 19, 2014

### 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

Lin-Zhi International, Inc.  
670 Almanor Avenue  
Sunnyvale, CA 94085  
Phone: (408) 732-3856  
Fax: (408) 732-3849  
e-mail: bclin@lin-zhi.com

Contact: Bernice Lin, Ph.D.  
VP Operations

### Device Name and Classification

Classification Name: Enzyme Immunoassay, Oral Fluid Methamphetamine  
Class II, LAF (91 Toxicology),  
21 CFR 862.3610

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 Oral Fluid Methamphetamine Enzyme  
Immunoassay

Proprietary Name: LZI Oral Fluid Methamphetamine Enzyme Immunoassay,  
LZI Oral Fluid Methamphetamine Calibrators  
LZI Oral Fluid Methamphetamine Controls

## **Legally Marketed Predicate Device(s)**

The LZI Oral Fluid Methamphetamine Enzyme Immunoassay (k131652) is substantially equivalent to the Lin-Zhi International, Inc. Oral Fluid Methamphetamine Enzyme Immunoassay, Calibrators and Controls for Hitachi 717 Systems (k062242) manufactured by Lin-Zhi International, Inc. The LZI Oral Fluid Methamphetamine 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 Oral Fluid Methamphetamine assay is a homogeneous enzyme immunoassay with 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, methamphetamine-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 methamphetamine-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 Oral Fluid Methamphetamine Enzyme Immunoassay is a kit comprised of two reagents, an R<sub>1</sub> and R<sub>2</sub> which are bottled separately but sold together within the kit.

The R<sub>1</sub> solution contains mouse monoclonal anti-methamphetamine antibody, glucose-6-phosphate (G6P) nicotinamide adenine dinucleotide (NAD), stabilizers, and sodium azide (0.09%) as a preservative. The R<sub>2</sub> solution contains glucose-6-phosphate dehydrogenase (G6PDH) labeled with methamphetamine in buffer with sodium azide (0.09%) as preservative.

The LZI Oral Fluid Methamphetamine Enzyme Immunoassay calibrators and controls designated for use at the 50 ng/mL cutoffs contain 0, 20, 37.5, 50, 62.5, 100, and 140 ng/mL of d-methamphetamine in human oral fluid with sodium azide (0.09%) as preservative. These five calibrators and two controls are sold as individual bottles.

The LZI Oral Fluid Collector is a 50 mL polypropylene collection tube. It is a non-sterile centrifuge tube with a screw-on cap and printed graduations (United Lab Plastics, Catalog#UP2262).

## **Intended Use**

The LZI Oral Fluid Methamphetamine Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of d-methamphetamine in neat human oral fluid, collected into the LZI Oral Fluid Collector, at the cutoff value 50 ng/mL. The assay is designed for prescription 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 Oral Fluid Methamphetamine Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Oral Fluid Methamphetamine Enzyme Immunoassay at the cutoff value 50 ng/mL.

The LZI Oral Fluid Methamphetamine Controls are for use as assayed quality control materials to monitor the precision of the LZI Oral Fluid Methamphetamine Enzyme Immunoassay at the cutoff value of 50 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 LZI Oral Fluid Methamphetamine Enzyme Immunoassay (k131652) is substantially equivalent to the Lin-Zhi International, Inc. Oral Fluid Methamphetamine Enzyme Immunoassay, Calibrators and Controls for Hitachi 717 Systems cleared by the FDA under the premarket notification k062242 for its stated intended use.

The following table compares LZI's Oral Fluid Methamphetamine Enzyme Immunoassay (k131652) with the predicate device.

<b>Device Characteristics</b>	<b>Subject Device (k131652)</b> LZI Oral Fluid Methamphetamine Enzyme Immunoassay, Calibrators and Controls	<b>Predicate Device (k062242)</b> LZI Oral Fluid Methamphetamine Enzyme Immunoassay, Calibrators and Controls
<b>Intended Use</b>	<p>The LZI Oral Fluid Methamphetamine Enzyme Immunoassay, is intended for the qualitative and semi-quantitative determination of d-methamphetamine in neat human oral fluid, collected into the LZI Oral Fluid Collector, at the cutoff value 50 ng/mL. The assay is designed for prescription use with a number of automated clinical chemistry analyzers.</p> <p><i>This assay provides a rapid screening procedure for determining the presence of d-methamphetamine in oral fluid. 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 Methamphetamine Enzyme Immunoassays for Drugs of Abuse in Oral Fluid is a homogeneous enzyme immunoassay system to detect methamphetamine in human saliva with a cutoff of 45 ng/mL when testing oral fluid specimen collected with Salivette collector (manufactured by Sarstedt) and diluted with 1 mL of buffer. The calibrators and controls of the analyte (d-methamphetamine) are prepared with oral fluid buffer so that it can be used to verify and validate the assay. The assay is intended for use in the qualitative determination for methamphetamine. The assay is designed for professional use with a number of automated clinical chemistry analyzers.</p> <p><i>The Oral Fluid Methamphetamine Enzyme Immunoassay is a homogeneous enzyme immunoassay system provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/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.</i></p>
<b>Analyte</b>	d-methamphetamine	d-methamphetamine
<b>Cutoff</b>	50 ng/mL	45 ng/mL
<b>Matrix</b>	Oral fluid	Oral fluid
<b>Calibrator Levels</b>	5 Levels (0, 20, 50, 100, 140 ng/mL)	5 Levels (0, 15, 30, 45, 90 ng/mL)
<b>Control Levels</b>	2 Levels (37.5 ng/mL, 62.5 ng/mL)	2 Levels (15 ng/mL, 45 ng/mL)
<b>Storage</b>	2-8 °C until expiration date	2-8 °C until expiration date

## Performance Characteristics Summary:

### Hitachi 717 Analyzer

#### Semi-Quantitative Positive/Negative Results:

Sample Concentration	Within Run		Total Precision	
	Number of Determination	Immunoassay Result	Number of Determination	Immunoassay Result
0 ng/mL	22	22 Negative	88	88 Negative
12.5 ng/mL	22	22 Negative	88	88 Negative
25 ng/mL	22	22 Negative	88	88 Negative
37.5 ng/mL	22	22 Negative	88	88 Negative
62.5 ng/mL	22	22 Positive	88	88 Positive
75 ng/mL	22	22 Positive	88	88 Positive
87.5 ng/mL	22	22 Positive	88	88 Positive
100 ng/mL	22	22 Positive	88	88 Positive

#### Qualitative Positive/Negative Results:

Sample Concentration	Within Run		Total Precision	
	Number of Determination	Immunoassay Result	Number of Determination	Immunoassay Result
0 ng/mL	22	22 Negative	88	88 Negative
12.5 ng/mL	22	22 Negative	88	88 Negative
25 ng/mL	22	22 Negative	88	88 Negative
37.5 ng/mL	22	22 Negative	88	88 Negative
62.5 ng/mL	22	22 Positive	88	88 Positive
75 ng/mL	22	22 Positive	88	88 Positive
87.5 ng/mL	22	22 Positive	88	88 Positive
100 ng/mL	22	22 Positive	88	88 Positive

#### Linearity:

Hitachi 717 Instrument: 5 - 140 ng/mL

When using drug-free samples spiked with known amounts of d-methamphetamine and comparing the result (y) and target (x) value, using the least squares regression technique, the regression equation and correlation are as follow:

$$y = 0.9834x - 0.9874, r^2 = 0.9993$$

#### Method Comparison: Clinical Samples

From a total of eighty-five (85) clinical unaltered samples

For both Qualitative and Semi-Quantitative results:

100.0 % agreement with positive, 95.2 % agreement with negative samples

#### Endogenous Compound Interference and Specificity - Cross-Reactivity:

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

**Shipping/Recovery Stability Study:**

No significant sample degradation occurred following real-time and accelerated stability studies up to 72 hours. All sample shipments are based on the assumption of a 24 hour priority overnight delivery.

**Sample Storage Stability Study:**

No significant sample degradation occurred following real-time and accelerated stability studies up to 13 Days. Based on real-time studies, samples can be stored at 2-8 °C for up to 15 Days. Based on the Arrhenius equation, accelerated stability data supports at least 18 months of shelf-life storage at -20 °C. Real-time stability studies are on-going.

**Open (and re-capped) vial Stability for Calibrator/Control:**

Real time (2 - 8 °C) and accelerated stability studies (at room temperature and 30 °C) were carried out for 17 months (508 Days) and results indicated degradation at all three conditions was minimal. Thermal stability data supports at least 18 months of shelf life storage at 2 - 8 °C.

**Summary:**

The information provided in this pre-market notification demonstrates that the LZI Oral Fluid Methamphetamine Enzyme Immunoassay (k131652) 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 Oral Fluid Methamphetamine Enzyme Immunoassay is substantially equivalent to the predicate device in terms of safety and effectiveness for its stated 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

March 21, 2014

LIN-ZHI INTERNATIONAL, INC.  
BERNICE LIN  
VP OF OPERATIONS  
670 ALMANOR AVE  
SUNNYVALE CA 94085

Re: K131652

Trade/Device Name: LZI Oral Fluid Methamphetamine Enzyme Immunoassay, Calibrators,  
LZI Oral Fluid Methamphetamine Calibrators  
LZI Oral Fluid Methamphetamine Controls

Regulation Number: 21 CFR 862.3600

Regulation Name: Methamphetamine test system

Regulatory Class: II

Product Code: LAF, DLJ, LAS

Dated: December 18, 2013

Received: December 23, 2013

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. 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

**Indications for Use**

510(k) Number (if known)  
k131652

**Device Name**

LZI Oral Fluid Methamphetamine Enzyme Immunoassay LZI Oral Fluid Methamphetamine Calibrators LZI Oral Fluid Methamphami

**Indications for Use (Describe)**

The LZI Oral Fluid Methamphetamine Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of d-methamphetamine in neat human oral fluid, collected into the LZI Oral Fluid Collector, at the cutoff value of 50 ng/mL. The assay is designed for prescription use with a number of automated clinical chemistry analyzers.

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 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 Oral Fluid Methamphetamine Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Oral Fluid Methamphetamine Enzyme Immunoassay at the cutoff value of 50 ng/mL.

The LZI Oral Fluid Methamphetamine Controls are for use as assayed quality control materials to monitor the precision of the LZI Oral Fluid Methamphetamine Enzyme Immunoassay at the cutoff value of 50 ng/mL.

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