K062242

SEP 29 2006

# 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


Lin-Zhi International, Inc.
687 North Pastoria Avenue
Sunnyvale, CA 94085
Phone: (408) 732-3856
Fax: (408) 732-3849
Email: mtlin@lin-zhi.com

Contact: Marie Lin, Ph.D.
President, R&D Director


## Device Name and Classification

Classification Name: The Methamphetamine test systems have been placed in Class II by the Bureau of Medical Devices.
Classification Number: LAF (21 CFR ~~862.3600~~ 862.3610)
Panel: 91Toxicology

The "Drug Specific, Calibrators" has been placed in Class II by the Bureau of Medical Devices.
Classification No.: DLJ, 21 CFR 862.3200
Panel: 91Toxicology

The "Single (Specified) Analyte Controls" has been placed in Class I by the Bureau of Medical Devices.
Classification No.: LAS, 21 CFR 862.3280
Panel: 91Toxicology

Common Name: Oral Fluid Methamphetamine Homogeneous Enzyme Immunoassays

Proprietary Name:

## Legally Marketed Predicate Device(s)

The LZI Oral Fluid Methamphetamine Enzyme Immunoassay is substantially equivalent to the Methamphetamine Intercept® Micro-plate EIA (K993208) manufactured by OraSure Technologies Inc. (formerly known as STC Technologies, Inc) for its general intended use. The current subject device is also substantially equivalent to other LZI test systems cleared by FDA, e.g., the Oral Fluid Cocaine (K0509045), Opiate (K050988), and Methadone (K051058) Homogeneous Enzyme Immunoassay for its stated intended use.

## Device Description

LZI's Oral Fluid Methamphetamine Enzyme Immunoassay is a ready-to-use, liquid reagent, homogeneous enzyme immunoassay. The assay uses specific antibodies that can detect methamphetamine in oral fluid with minimal cross-reactivity to various, common prescription drugs and abused drugs. The assay is based on competition between drug labeled with glucose-6-phosphate dehydrogenase (G6PDH) enzyme and free drug from the saliva sample for a fixed amount of specific antibody. In the absence of free drug from the saliva sample the specific antibody binds to the drug labeled G6PDH enzyme causing a decrease in enzyme activity. It is therefore the drug concentration is proportional to the enzyme activity. The G6PDH enzyme activity is determined spectrophotometrically at 340 nm by measuring its ability to covert nicotinamide adenine dinucleotide (NAD) to NADH.

## Intended Use

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.

***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.***

## Comparison to Predicate Device(s)

The LZI Oral Fluid Methamphetamine Homogeneous Enzyme Immunoassay, including calibrators and controls, is substantially equivalent to OraSure's Methamphetamine Intercept® Micro-plate EIA in its intended use and in for the qualitative determination of methamphetamine in human oral fluid.

| Device Characteristics | Subject Device (LZI Oral Fluid Methamphetamine Homogeneous EIA) | Predicate Device (OraSure Methamphetamine Intercept® Micro-plate EIA) |
|---|---|---|
| **Intended Use** | 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.<br><br>***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.*** | The OraSure Methamphetamine Intercept® Micro-plate EIA is intended for use by clinical laboratories in the qualitative determination of methamphetamine in oral fluid collected with the Intercept® DOA Oral Specimen Collection Device using a 40 ng/mL cutoff. For *In Vitro* Diagnostic Use.<br><br>***The OraSure Methamphetamine Intercept® Micro-plate EIA provides only a preliminary analytical test result. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drugs of abuse test result, particularly when a preliminary, positive result is observed.*** |
| **Analyte** | d-methamphetamine | d-methamphetamine |
| **Matrix** | Saliva | Saliva |
| **Calibrators/ Controls Level** | 5 levels including a negative | 4 levels including a negative |

The LZI Oral Fluid Methamphetamine Homogeneous Enzyme Immunoassay, including calibrators and controls, is also substantially equivalent to other LZI test systems cleared by FDA, e.g., the Oral Fluid Cocaine (K0509045), Opiate (K050988), and Methadone (K051058) Homogeneous Enzyme Immunoassay for its stated intended use.

| **Device Characteristics** | **Predicate Device (K0509045)** | **Predicate Device (K0509088)** | **Predicate Device (K051058)** |
|---|---|---|---|
| **Intended Use** | The LZI Cocaine Metabolite (Benzoylecgonine) Oral Fluid Homogeneous EIA is a homogeneous enzyme immunoassay system to detect cocaine metabolite in human saliva with a cutoff of 15 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 (Benzoylecgonine) 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 cocaine/cocaine metabolite drugs.<br><br>***The Cocaine Metabolite (Benzoylecgonine) Oral Fluid 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.*** | The LZI Opiate Oral Fluid Homogeneous EIA is a homogeneous enzyme immunoassay system to detect opiates in human saliva with a cutoff of 30 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 (Opiate) 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 Opiate drugs.<br><br>***The Opiate Oral Fluid 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 judgement should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.*** | The LZI Methadone Oral Fluid Homogeneous EIA is a homogeneous enzyme immunoassay system to detect methadone in human saliva with a cutoff of 30 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 (Methadone) 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 Methadone drugs.<br><br>***The Methadone Oral Fluid 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 judgement should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.*** |
| **Analyte** | Benzoylecgonine | Morphine | Methadone |
| **Matrix** | Saliva | Saliva | Saliva |
| **Calibrators/ Controls Level** | 5 levels including a negative | 5 levels including a negative | 5 levels including a negative |

## Performance Characteristics

### LZI Oral Fluid Methamphetamine Assay

| Feature | Oral Fluid Methamphetamine EIA | | | |
|---|---|---|---|---|
| **Qualitative : (n=120) mA/min** | | **Mean.** | **SD** | **% CV** |
| **Within Run Precision:** | Negative | 284.8 | 1.83 | 0.64 % |
| | 15 ng/mL | 332.0 | 1.82 | 0.55 % |
| | 30 ng/mL | 351.9 | 1.84 | 0.52 % |
| | 45 ng/mL | 373.2 | 1.97 | 0.53 % |
| | 90 ng/mL | 400.4 | 1.54 | 0.39 % |
| | | **Mean.** | **SD** | **% CV** |
| **Total Precision:** | Negative | 284.8 | 2.27 | 0.80 % |
| | 15 ng/mL | 332.0 | 2.13 | 0.64 % |
| | 30 ng/mL | 351.9 | 2.13 | 0.60 % |
| | 45 ng/mL | 373.2 | 2.50 | 0.67 % |
| | 90 ng/mL | 400.4 | 2.33 | 0.58 % |
| **Accuracy:** Clinical patients samples (n=112) vs. GC/MS | 98.2 % Agreement | | | |
| **Specificity:** | See attached Assay package insert | | | |

### OraSure Methamphetamine Micro=Plate EIA

| Feature | Methamphetamine | Mean O.D. | % CV |
|---|---|---|---|
| Precision | 0 ng/mL | 2.056 | 7.8 |
| Intra-assay N=64 | 20 ng/mL | 0.978 | 7.0 |
| | 40 ng/mL | 0.710 | 6.2 |
| | 60 ng/mL | 0.554 | 7.8 |
| | 80 ng/mL | 0.480 | 6.4 |
| Inter-assay N=4/day, 20 days | 0 ng/mL | 2.056 | 7.5 |
| | 20 ng/mL | 0.978 | 7.7 |
| | 40 ng/mL | 0.710 | 7.9 |
| | 60 ng/mL | 0.554 | 7.5 |
| | 80 ng/mL | 0.480 | 8.4 |
| | | | |
| Accuracy: Clinical patients sample (n=50) vs. GC/MS | 98 % Agreement | | |
| Specificity | See OraSure product insert | | |

## Summary

The information provided in this pre-market notification demonstrates that the LZI Oral Fluid Methamphetamine Homogeneous EIA is substantially equivalent to the legally marketed predicated device for its general intended use. Data and results provided in this premarket notification were collected and prepared in accordance with the NCCLS guidance. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available predicate device as confirmed by gas chromatography/mass spectrometry, an independent analytical method. The information supplied in this pre-market notification provides reasonable assurance that the LZI Oral Fluid Methamphetamine Homogeneous EIA is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 29 2006

Marie Lin, Ph.D.
President, R&D Director
Lin-Zhi International, Inc.
687 North Pastoria Avenue
Sunnyvale, CA 94085

Re: k062242
[redacted] Oral Fluid Methamphetamine Homogeneous Enzyme Immunoassay, Calibrators and Controls
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: LAF, DLJ, LAS
Dated: July 31, 2006
Received: August 2, 2006

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.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, 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

510(k) Number (if known): K062242

Device Name: Oral Fluid Methamphetamine Homogeneous Enzyme Immunoassay, Calibrators and Controls.

Indications For Use:

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.

***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.***

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062242