FEB 2 1 2014

k133710

# 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.
670 Almanor Avenue
Sunnyvale, CA 94085
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Contact: Bernice Lin, Ph.D.
VP Operations

## Submission Date

February 21, 2014

## Multi-calibrator Set A, B, and C Device Name and Classification

Multi-calibrator Set A:

| | |
|---|---|
| Classification Name: | Drug Mixture Calibrator Materials<br>Class II, DKB (91 Toxicology),<br>21 CFR862.3200 |
| Common Name: | Benzoylecgonine, Methamphetamine, Methadone, and 6-acetylmorphine Calibrators |
| Proprietary Name: | LZI Multiple Analyte Set A Drugs of Abuse Calibrators |
| Classification Name: | Drug Mixture Control Materials<br>Class I, DIF (91 Toxicology),<br>21 CFR 862.3280 |
| Common Name: | Benzoylecgonine, Methamphetamine, Methadone, and 6-acetylmorphine Controls |
| Proprietary Name: | LZI Multiple Analyte Set A Drugs of Abuse Controls |

Multi-calibrator Set B:

| | |
|---|---|
| Classification Name: | Drug Mixture Calibrator Materials<br>Class II, DKB (91 Toxicology),<br>21 CFR862.3200 |
| Common Name: | MDMA, Morphine, Oxazepam, and Secobarbital Calibrators |
| Proprietary Name: | LZI Multiple Analyte Set B Drugs of Abuse Calibrators |
| Classification Name: | Drug Mixture Control Materials<br>Class I, DIF (91 Toxicology),<br>21 CFR 862.3280 |
| Common Name: | MDMA, Morphine, Oxazepam, and Secobarbital Controls |
| Proprietary Name: | LZI Multiple Analyte Set B Drugs of Abuse Controls |

Multi-calibrator Set C:

| | |
|---|---|
| Classification Name: | Drug Mixture Calibrator Materials<br>Class II, DKB (91 Toxicology),<br>21 CFR862.3200 |
| Common Name: | Benzoylecgonine, Methamphetamine, Methadone, Morphine, Oxazepam, and Secobarbital Calibrators |
| Proprietary Name: | LZI Multiple Analyte Set C Drugs of Abuse Calibrators |
| Classification Name: | Drug Mixture Control Materials<br>Class I, DIF (91 Toxicology),<br>21 CFR 862.3280 |
| Common Name: | Benzoylecgonine, Methamphetamine, Methadone, Morphine, Oxazepam, and Secobarbital Controls |
| Proprietary Name: | LZI Multiple Analyte Set C Drugs of Abuse Controls |

## Previous Submission Information

There were no prior submissions for this subject device (k133710).

## Legally Marketed Predicate Device(s)

The LZI Multiple Analyte Set A, B, and C Drugs of Abuse Calibrators and Controls (k133710) are substantially equivalent to the Multiple Analyte Drugs of Abuse Calibrators and Controls (k051088) manufactured by Lin-Zhi International, Inc. The LZI Multiple Analyte Set A, B, and C Drugs of Abuse Calibrators and Controls are identical or similar to its predicate in terms of intended use, method principle, device components, and clinical performance.

## Device Description

All of the LZI Multiple Analyte Set A, B, and C Drugs of Abuse Calibrators and Controls are liquid and ready to use. These Calibrators and Controls do not have any especially unique technical characteristics. Each contains a known concentration of a specific drug analyte as a mixture.

The Negative DAU Calibrator is a processed, drug-free human urine matrix in human urine with sodium azide (0.09%) as preservative. The Low, Cutoff, Intermediate, and High Calibrators, as well as the 2 levels of Controls are prepared by spiking known concentrations of drug analyte into the Negative DAU Calibrator matrix. These five calibrators and two controls are sold as individual bottles. The various concentrations of each drug analyte in their corresponding calibrators and controls are summarized as follows:

Table 1: LZI Multiple Analyte Set A Calibrators and Controls:

| | Low Calibrator | Cutoff Calibrator | Intermediate Calibrator | High Calibrator | | Control Level 1 | Control Level 2 |
|---|---|---|---|---|---|---|---|
| **Material** | ng/mL | ng/mL | ng/mL | ng/mL | | ng/mL | ng/mL |
| Benzoylecgonine | 75 | 150 | 300 | 1000 | | 112.5 | 187.5 |
| d-Methamphetamine | 250 | 500 | 750 | 1000 | | 375 | 625 |
| Methadone | 150 | 300 | 600 | 1000 | | 225 | 375 |
| 6-AM | 5 | 10 | 20 | 40 | | 7.5 | 12.5 |

** 5th Calibrator is the Negative Calibrator*

Table 2: LZI Multiple Analyte Set B Calibrators and Controls:

| | Low Calibrator | Cutoff Calibrator | Intermediate Calibrator | High Calibrator | Control Level 1 | Control Level 2 |
|---|---|---|---|---|---|---|
| **Material** | ng/mL | ng/mL | ng/mL | ng/mL | ng/mL | ng/mL |
| MDMA | 250 | 500 | 750 | 1000 | 375 | 625 |
| Morphine | 1000 | 2000 | 4000 | 6000 | 1500 | 2500 |
| Oxazepam | 100 | 200 | 500 | 1000 | 150 | 250 |
| Secobarbital | 100 | 200 | 500 | 1000 | 150 | 250 |

** 5th Calibrator is the Negative Calibrator*

Table 3: LZI Multiple Analyte Set C Calibrators and Controls:

| | Low Calibrator | Cutoff Calibrator | Intermediate Calibrator | High Calibrator | | Control Level 1 | Control Level 2 |
|---|---|---|---|---|---|---|---|
| **Material** | ng/mL | ng/mL | ng/mL | ng/mL | | ng/mL | ng/mL |
| Benzoylecgonine | 75 | 150 | 300 | 1000 | | 112.5 | 187.5 |
| d-Methamphetamine | 250 | 500 | 750 | 1000 | | 375 | 625 |
| Methadone | 150 | 300 | 600 | 1000 | | 225 | 375 |
| Morphine | 1000 | 2000 | 4000 | 6000 | | 1500 | 2500 |
| Oxazepam | 100 | 200 | 500 | 1000 | | 150 | 250 |
| Secobarbital | 100 | 200 | 500 | 1000 | | 150 | 250 |

** 5th Calibrator is the Negative Calibrator*

## Intended Use

Device Name: LZI Multiple Analyte Set A, B, and C Urine Drugs of Abuse Calibrators

The LZI Multiple Analyte Set A, B, and C Urine Drugs of Abuse Calibrators are intended for in vitro diagnostic use for the calibration of assays for the analytes currently listed in the package insert: Benzoylecgonine, Methamphetamine, Methadone, 6-acetylmorphine, MDMA, Morphine, Oxazepam, and Secobarbital. The calibrators are designed for prescription use with homogeneous enzyme immunoassays on automated clinical chemistry analyzers.

Device Name: LZI Multiple Analyte Set A, B, and C Urine Drugs of Abuse Controls

The LZI Multiple Analyte Set A, B, and C Urine Drugs of Abuse Controls are intended for in vitro diagnostic use to monitor the performance of assays for the analytes currently listed in the package insert: Benzoylecgonine, Methamphetamine, Methadone, 6-acetylmorphine, MDMA, Morphine, Oxazepam, and Secobarbital. The controls are designed for prescription use with homogeneous enzyme immunoassays on automated clinical chemistry analyzers.

## Comparison to Predicate Device

The LZI Multiple Analyte Set A, B, and C Drugs of Abuse Calibrators and Controls (k133710) are substantially equivalent to the Multiple Analyte Drugs of Abuse Calibrators and Controls (k051088) manufactured by Lin-Zhi International, Inc. The LZI Multiple Analyte Set A Drugs of Abuse Calibrators and Controls are identical or similar to its predicate in terms of intended use, method principle, device components, and clinical performance

All spiked values of calibrators and controls were confirmed with GC/MS. Performance characteristics on precision, accuracy and stability are acceptable. The following table compares LZI Multiple Analyte Set A, B, and C Drugs of Abuse Calibrators and Controls with the predicate device.

| **Device Characteristics** | **Subject Device** (k133710) LZI Multiple Analyte Set **A** DAU Calibrators and Controls | **Subject Device** (k133710) LZI Multiple Analyte Set **B** DAU Calibrators and Controls | **Subject Device** (k133710) LZI Multiple Analyte Set **C** DAU Calibrators and Controls | **Predicate Device** (k051088) LZI Multiple Analyte DAU Calibrators and Controls |
|---|---|---|---|---|
| **Intended Use** | Intended for in vitro diagnostic use for the calibration and validation of LZI DAU enzyme immunoassays to detect benzoylecgonine, methamphetamine, methadone, and 6-acetylmorphine, in human urine. ***The assays used with the multiple analyte calibrators and controls only provide 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.*** | Intended for in vitro diagnostic use for the calibration and validation of LZI DAU enzyme immunoassays to detect MDMA, morphine, oxazepam, and secobarbital in human urine. ***The assays used with the multiple analyte calibrators and controls only provide 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.*** | Intended for in vitro diagnostic use for the calibration and validation of LZI DAU enzyme immunoassays to detect benzoylecgonine, methamphetamine, methadone, morphine, oxazepam, and secobarbital in human urine. ***The assays used with the multiple analyte calibrators and controls only provide 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.*** | Intended for in vitro diagnostic use for the calibration and validation of LZI DAU enzyme immunoassays to detect methamphetamine, opiate, phencyclidine, benzoylecgonine, benzodiazepines, barbiturates, methadone, and propoxyphene in human urine. |

## Comparison to Predicate Device (continued)

| Device Characteristics | Subject Device (k133710) LZI Multiple Analyte Set A DAU Calibrators and Controls | Subject Device (k133710) LZI Multiple Analyte Set B DAU Calibrators and Controls | Subject Device (k133710) LZI Multiple Analyte Set C DAU Calibrators and Controls | Predicate Device (k051088) LZI Multiple Analyte DAU Calibrators and Controls |
|---|---|---|---|---|
| **Analyte** | benzoylecgonine,<br>d-methamphetamine,<br>methadone,<br>6-acetylmorphine | morphine,<br>oxazepam,<br>secobarbital,<br>MDMA | benzoylecgonine<br>d-methamphetamine,<br>methadone,<br>morphine,<br>oxazepam,<br>secobarbital | benzoylecgonine,<br>d-methamphetamine,<br>methadone,<br>morphine,<br>oxazepam,<br>secobarbital,<br>phencyclidine,<br>propoxyphene |
| **Materials are applicable for assays with the cutoff concentrations listed (ng/mL)** | COC - 150<br>MAMP or AMP - 500<br>MTD - 300<br>6AM - 10 | OPI – 2,000<br>BZO - 200<br>BARB - 200<br>MDMA - 500 | COC – 150<br>MAMP or AMP - 500<br>MTD - 300<br>OPI – 2,000<br>BZO - 200<br>BARB - 200 | COC - 150<br>MAMP or AMP - 500<br>MTD - 300<br>OPI – 2,000<br>BZO- 200<br>BARB- 200<br>PCP- 25<br>PPX- 300 |
| **Matrix** | Urine | Urine | Urine | Urine |
| **Calibrators Level** | 5 Levels – See Table 1 (under "Device Description") | 5 Levels – See Table 2 (under "Device Description") | 5 Levels – See Table 3 (under "Device Description") | 5 Levels – See Table 4 (below) |
| **Controls Level** | 2 Levels - See Table 1 (under "Device Description") | 2 Levels - See Table 2 (under "Device Description") | 2 Levels - See Table 3 (under "Device Description") | 2 Levels - See Table 4 (below) |
| **Storage** | 2-8 °C until expiration date | 2-8 °C until expiration date | 2-8 °C until expiration date | 2-8 °C until expiration date |

Table 4: Predicate Multiple Analyte Calibrators and Controls (k051088)

| | Low Calibrator | Cutoff Calibrator | Intermediate Calibrator | High Calibrator | | Control Level 1 | Control Level 2 |
|---|---|---|---|---|---|---|---|
| **Material** | ng/mL | ng/mL | ng/mL | ng/mL | | ng/mL | ng/mL |
| d-Methamphetamine | 250 | 500 | 750 | 1000 | | 375 | 625 |
| Morphine | 1000 | 2000 | 4000 | 6000 | | 1500 | 2500 |
| Phencyclidine | 12.5 | 25 | 50 | 100 | | 18 | 35 |
| Benzoylecgonine | 75 | 150 | 300 | 1000 | | 110 | 190 |
| Oxazepam | 100 | 200 | 500 | 1000 | | 100 | 300 |
| Secobarbital | 100 | 200 | 500 | 1000 | | 100 | 300 |
| Propoxyphene | 150 | 300 | 600 | 1000 | | 225 | 375 |
| Methadone | 150 | 300 | 600 | 1000 | | 225 | 375 |

** 5th Calibrator is the Negative Calibrator*

## Performance Characteristics Summary:

### Multiple Analyte Sets A,B, and C Drugs of Abuse Calibrators and Controls Stability:

Based on the largest % change for any individual concentration or % change in Total Separation (versus Day 0 measurements) at Cold (2-8 °C), Room Temperature, and Accelerated (30 °C) Temperature studies, the LZI Multiple Analyte Set A, B, and C Drugs of Abuse Calibrators and Controls did not vary greater than ±10%. In Set A, the only analyte for which this differed was the 6- acetylmorphine (6AM) Calibrator and Control. In Set B and C, the only analyte for which this differed was the Benzodiazepine (Oxazepam) Calibrator and Control. All calibrators and controls held steady when stored at 2 °C to 8 °C (refrigerated) up to Day 366 real time. Based on these data we have capped our predicted shelf-life to the current cold temperature real-time study for the LZI Multiple Analyte Sets A, B, and C Drugs of Abuse Calibrators and Controls to at least 12 months.

### Traceability and Value Assignment:

The starting materials for the calibrators and controls were commercially available standard stock solutions in methanol. The standard solution was found to be 99% in purity, analyzed by GC/MS. Secondary stock solutions were prepared using negative urine calibrator matrix and the concentrations were verified gravimetrically using balances calibrated with NIST traceable weights. The secondary stock solutions were then spiked into the negative urine calibrator matrix to the desired concentration and verified by GC/MS to be within ± 10% of the target concentration.

### Summary:

The information provided in this pre-market notification demonstrates that the LZI Multiple Analyte Sets A, B, and C Drugs of Abuse Calibrators and Controls are 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 chromatography/mass spectrometry (GC/MS), an independent analytical method. The information supplied in this pre-market notification provides reasonable assurance that the The LZI Multiple Analyte Sets A, B, and C Drugs of Abuse Calibrators and Controls are safe and effective 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

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

February 21, 2014

Re: K133710
Trade/Device Name: Lin-Zhi Multiple Analyte Set A, B and C Urine Drugs of Abuse Calibrators
Lin-Zhi Multiple Analyte Set A, B and C Urine Drugs of Abuse Controls
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: II
Product Code: DKB, DIF
Dated: December 2, 2013
Received: December 4, 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,

Ruth A. Chesler -S

for
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
k133710

Device Name
Lin-Zhi Multiple Analyte Set A, B, and C Urine Drugs of Abuse Calibrators; Lin-Zhi Multiple Analyte Set A, B, and C Urine Drugs of Abuse Controls

Indications for Use *(Describe)*

The Lin-Zhi Multiple Analyte Set A, B, and C Urine Drugs of Abuse Calibrators are intended for in vitro diagnostic use for the calibration of assays for the analytes currently listed in the package insert: Benzoylecgonine, Methamphetamine, Methadone, 6-acetylmorphine, MDMA, Morphine, Oxazepam, and Secobarbital. The calibrators are designed for prescription use with homogeneous enzyme immunoassays on automated clinical chemistry analyzers.

The Lin-Zhi Multiple Analyte Set A, B, and C Urine Drugs of Abuse Controls are intended for in vitro diagnostic use to monitor the performance of assays for the analytes currently listed in the package insert: Benzoylecgonine, Methamphetamine, Methadone, 6-acetylmorphine, MDMA, Morphine, Oxazepam, and Secobarbital. The controls are designed for prescription use with homogeneous enzyme immunoassays 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

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