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K023316

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: Chiu Chin Chang, Ph.D.
VP, R&D

Device Name and Classification

(a) Classification Name:	Calibrators, Drug Specific; Class II, DLJ (91 Toxicology), 21 CFR 862.3200
Common/Usual Name:	Methadone Calibrators Propoxyphene Calibrators
Proprietary Name:	None
(b) Classification Name:	Drug Specific Control Materials; Class I, LAS (91 Toxicology), 21 CFR 862.3280
Common/Usual Name:	Methadone Controls Propoxyphene Controls
Proprietary Name:	None

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.'s Single Analyte (Methadone or Propoxyphene) Urine Drugs of Abuse Calibrators and Controls are substantially equivalent to the Drugs of Abuse Urine Calibrators A and Controls A (Diagnostic Reagents, Inc., now Microgenics Corporation), cleared under premarket notifications (K983159) for Drugs of Abuse Urine Calibrators and Controls.

Device Description

All of the Single Analyte Urine DAU Calibrators and Controls are human urine-based 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.

The Negative DAU calibrator is a processed, drug-free human urine matrix. 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. The various concentrations of each drug analyte in their corresponding calibrators and controls are summarized as follows:

	Propoxyphene EIA	**Methadone EIA**
Reference Material	Propoxyphene	Methadone
Low Calibrator	150 ng/mL	150 ng/mL
Cutoff Calibrator	300 ng/mL	300 ng/mL
Intermediate Calibrator	600 ng/mL	600 ng/mL
High Calibrator	1000 ng/mL	1000 ng/mL
Control Level 1	225 ng/mL	225 ng/mL
Control Level 2	375 ng/mL	375 ng/mL

Intended Use

The Methadone or Propoxyphene Urine DAU Calibrators are intended for in vitro diagnostic use for the calibration of their respective enzyme immunoassays to detect methadone or propoxyphene in human urine.

The Methadone or Propoxyphene Urine DAU Controls are intended for in vitro diagnostic use for the validation of their respective enzyme immunoassays to detect methadone or propoxyphene in human urine.

Comparison to Predicate Device

LZI's Single Analyte (Methadone or Propoxyphene) Urine DAU Calibrators and Controls are similar in intended use, matrix, and performance to the DRI's Drugs of Abuse Urine Calibrators A and Controls A.

Similarities:

- Both are for the calibration and validation of DAU enzyme immunoassay to detect drug of abuse in human urine.
- The cutoff concentration for either methadone or propoxyphene is the same, at 300 ng/mL.
- A total of 5 levels of calibrators including the negative calibrator for each analyte.
- The nominal concentrations of the analyte in the calibrators and controls are determined and confirmed by GC/MS.
- Both are urine-based liquids.
- Storage condition is the same, at 2°C to 8°C.
- Performance characteristics on precision, accuracy and stability are similar.

Differences:

Characteristics	DRI's Drugs of Abuse Urine Calibrators A and Controls A	LZI's Single Analyte Urine DAU Calibrators and Controls
No. of Analytes in Each Calibrator or Control	Multiple drugs in each Calibrator and Control	Single drug only in each Calibrator or Control.
No. of Calibrators	3 levels* including the Negative Calibrator	5 levels including the Negative Calibrator
Nomenclature/Labeling of Calibrators	Negative, Low (= Cutoff), and High	Negative, Low, Cutoff, Intermediate and High Calibrators
Concentration of Analyte	Methadone Controls: 200 and 375 ng/mL Propoxyphene Controls: 200 and 375 ng/mL	Methadone Controls: 225 and 375 ng/mL Propoxyphene Controls: 225 and 375 ng/mL

*Additional calibrators are now available. Currently 5 levels of calibrators (Cal 0, 1, 2, 3, and 4) are available from DRI/Microgenics Corp. under the product name "Multi-drug Urine Calibrators and Controls".

Conclusion

The information provided in the premarket notification demonstrates that the LZI's Methadone or Propoxyphene Urine Drugs of Abuse Calibrators and Controls are substantially equivalent to previously approved predicate devices, notably the DRI's Drugs of Abuse Urine Calibrators A and Controls A, and safe and effective for its intended use.

Performance Characteristics

Reproducibility (Precision)

Multiple vials each of the Calibrators and Controls were used during the evaluation of performance of the LZI's Methadone Enzyme Immunoassay and Propoxyphene Enzyme Immunoassay. The reproducibility, description of the assay principle, and assay procedure can be found on the package insert of each immunoassay.

The following tables illustrate the precision of each set of Single analyte Urine DAU Calibrators and Controls in their corresponding enzyme Immunoassays. Twelve vials each of Calibrators and Controls were used in immunoassay. The enzyme rates of the calibrators from each run and the concentrations of the controls determined from the calibration curves from the same run were summarized. Data on Methadone EIA were collected on the Synchron CX4CE Analyzer and data on Propoxyphene EIA were collected on the Hitachi 717 Analyzer.

Methadone EIA:

(N = 12)	Neg. Cal	Low Cal	Cutoff Cal	Intermediate Cal	High Cal
	0 ng/mL	150 ng/mL	300 ng/mL	600 ng/mL	1000 ng/mL
Ave. Rate	208.8	248.1	294.0	331.6	345.6
Stdev	0.9	2.1	3.0	2.6	1.3
%CV	0.4	0.8	1.0	0.8	0.4

(N =12)	Contl L_1	Contl L_2
	225 ng/mL	375 ng/mL
Ave. Conc.	228.0	379.6
Stdev	7.8	13.2
% CV	3.4	3.5

Propoxyphene EIA:

(N = 12)	Neg. Cal	Low Cal	Cutoff Cal	Intermediate Cal	High Cal
	0 ng/mL	150 ng/mL	300 ng/mL	600 ng/mL	1000 ng/mL
Ave. Rate	117.0	170.8	255.8	326.8	348.8
Stdev	0.8	1.4	2.3	1.9	2.5
%CV	0.6	0.8	0.9	0.6	0.7

(N =12)	Contl L_1	Contl L_2
	225 ng/mL	375 ng/mL
Ave. Conc.	232.6	378.0
Stdev	3.0	7.4
% CV	1.3	2.0

Accuracy

The concentrations of the LZI's Single Analyte (Methadone or Propoxyphene) Urine DAU Calibrators and Controls were determined and confirmed with gas chromatography/mass spectroscopy (GC/MS) technique. The observed concentration of the analyte in each calibrator or control, and its expected value are as follows:

	Methadone		Propoxyphene	
	Expected	**GC/MS**	**Expected**	**GC/MS**
Low Cal.	150	157	150	158
Cutoff Cal.	300	288	300	307
Intermediate Cal.	600	584	600	593
High Cal.	1000	963	1000	973
Level 1 Control	225	214	225	222
Level 2 Control	375	374	375	387

Methadone was purchased from Sigma and Aldrich, St. Louis, MO 63178 (Traceable to NIST standard.), and propoxyphene was purchased from Alltech Applied Science Lab., State College, PA 16801 (Traceable to USP reference standard.)

Stability

The LZI Methadone or Propoxyphene Urine DAU Calibrators and Controls were prepared according to established procedures. These Calibrators and Controls were stored at 2°C to 8°C (Refrigerated) at all times until use.

To assess long-term stability an accelerated temperature stability study was carried out at room temperature (RT) for 6 months. Calibrators and Controls stored at RT were then evaluated and compared to those counter parts stored at 2°C to 8°C (Refrigerated). The results indicated there is no significant difference between the two.

Real time stability at refrigerated temperature is being continued. The product shelf life is anticipated to be at least 12 months at 2°C to 8°C storage conditions. Calibrators and Controls prepared in artificial matrix without the urine component have been evaluated earlier, and showed more than 24 months real time stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 16 2002

Chiu Chin Chang, Ph.D.
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Lin-Zhi International, Inc.
687 North Pastoria Avenue
Sunnyvale, CA 94085

Re: k023316
Trade/Device Name: Single Analyte (Methadone or Propoxyphene) Urine Drugs of Abuse Calibrators and Controls
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical Toxicology Calibrator
Regulatory Class: Class II
Product Code: DLJ, LAS
Dated: September 30, 2002
Received: October 3, 2002

Dear Dr. Chang:

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 (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
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): K023316

Device Name: **Single Analyte (Methadone or Propoxyphene) Urine Drugs of Abuse Calibrators and Controls**

Indications for Use:

The Methadone or Propoxyphene Urine Drugs of Abuse Calibrators are intended for in vitro diagnostic use for the calibration of their respective enzyme immunoassays to detect methadone or propoxyphene in human urine.

The Methadone or Propoxyphene Urine Drugs of Abuse Controls are intended for in vitro diagnostic use for the validation of their respective enzyme immunoassays to detect methadone or propoxyphene in human urine.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Dean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023316