K032461
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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

Contact: Cheng-I Lin, Ph.D.
President

Device Name and Classification

Classification Name: Enzymatic method, Alcohol Dehydrogenase, Ultraviolet
Class II, DMT (21 CFR 862.3040)
(91 Toxicology),

Common Name: Ethyl Alcohol Enzymatic assay for the determination of Ethyl Alcohol levels in human serum, plasma or urine.

Proprietary Name: None

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.'s Ethyl Alcohol Enzymatic Assay is substantially equivalent to the Ethyl Alcohol Assay (By DRI/Microgenics Corp.), cleared under premarket notification K923783.

LZI's Ethyl Alcohol Enzymatic Assay is identical or similar to its predicate in terms of intended use, method principle, device components, and clinical performance.

Device Description

LZI's Ethyl Alcohol Enzymatic Assay is a ready-to-use, liquid reagent, homogeneous enzymatic assay. The assay uses ethyl alcohol specific enzyme, alcohol dehydrogenase

(ADH) that can detect ethyl alcohol in human urine, serum, plasma with minimal cross-reactivity to various, common prescription drugs and abused drugs.

The assay is based on alcohol dehydrogenase (ADH) enzyme uses ethyl alcohol as enzyme substrate. In the presence of nicotinamide adenine dinucleotide (NAD), ADH turns the ethyl alcohol to acetaldehyde and converts the NAD to NADH. The ADH enzyme activity is then determined spectrophotometrically at 340 nm by measuring its ability to covert nicotinamide adenine dinucleotide (NAD) to NADH.

$$\text{Ethyl Alcohol} + \text{NAD} \xrightleftharpoons{\text{ADH}} \text{NADH} + \text{Acetaldehyde}$$

Intended Use

The Ethyl Alcohol Enzymatic Assay is a homogeneous enzymatic assay with 0, 100 mg/dL calibrators. The assay is intended for quantitative analyses of for the determination of Ethyl Alcohol levels in human serum, plasma or urine.

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Comparison to Predicate Device

LZI's Ethyl Alcohol Enzymatic Assay is substantially equivalent to other products in commercially distribution intended for similar use. Most notably it is substantially equivalent to the currently, commercially marketed Ethyl Alcohol Assay (K923783) by DRI/Microgenics Corporation.

The following table compares LZI's Ethyl Alcohol Enzymatic Assay with the predicate device, Ethyl Alcohol Assay by DRI/Microgenics Corp.

Similarities:

- Both assays are for quantitative determination of Ethyl Alcohol levels in human serum, plasma or urine
- Both assays use the same method principle, and device components.

(Comparison to Predicate Device, continued)

Performance Characteristics

Feature	DRI's Ethyl Alcohol Test				LZI's Ethyl Alcohol Enzymatic Assay			
Within Run Precision:		Mean (mg/dL)	SD	% CV		Mean (mg/dL)	SD	% CV
	100 mg/dL	100.3	1.2	1.2	50 mg/dL	50.0	0.59	1.1
	50 mg/dL	48.6	1.3	2.7	100 mg/dL	99.1	0.77	0.8
	300 mg/dL	290.2	1.9	0.6	200 mg/dL	194.8	1.47	0.8
					300 mg/dL	281.6	3.21	1.1
Run-To-Run Precision:		Mean (mg/dL)	SD	% CV		Mean (mg/dL)	SD	% CV
	50 mg/dL	50.7	4.5	9.0	50 mg/dL	50.5	2.3	4.6
	250 mg/dL	253.7	6.7	2.6	100 mg/dL	99.2	0.56	0.58
					200 mg/dL	200.5	8.3	4.12
					300 mg/dL	280.0	8.26	2.95
Sensitivity:	10 mg/dL				3 mg/dL			
Accuracy:								
Urine specimens:	LZI = 1.003 DRI-0.95, (r^2=0.9998)				LZI = 1.003 DRI-0.95, (r^2=0.9998)			
Serum Samples:	LZI = 0.991 DRI-11.03, (r^2=0.9952)				LZI = 0.991 DRI-11.03, (r^2=0.9952)			
Analytical Recovery:	No data available				Average 95.0% recovery at 18.75 mg/dL Average 98.3% recovery at 37.5 mg/dL Average 102.4% recovery at 75 mg/dL Average 97.9% recovery at 150 mg/dL Average 96.9% recovery at 300mg/dL Average 95% recovery at 600 mg/dL			
Specificity:	See attached DRI's Ethyl Alcohol Assay				Comparable to the predicate device.			

Conclusion

LZI's Ethyl Alcohol Enzymatic Assay was evaluated for several performance characteristics including precision, sensitivity, accuracy, analytical recovery, and specificity. All the studies showed acceptable results when compared to the predicate device.

We trust the information provided in this Premarket Notification [510(k)] submission will support a determination of substantial equivalence of the LZI's Ethyl Alcohol Enzymatic Assay to other Ethyl Alcohol Assay systems currently marketed in the United States.

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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

Contact: Cheng-I Lin, Ph.D.
President

Device Name and Classification

Classification Name:	Calibrators, Drug Mixture; Class II, DKB (91 Toxicology), 21 CFR 862.3200
Common/Usual Name:	Ethyl Alcohol Calibrators and Controls
Proprietary Name:	None

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.'s Ethyl Alcohol Calibrators and Controls are substantially equivalent to EMIT Ethyl Alcohol Calibrators and Controls (Syva Co., now Dade Behring Limited), cleared under premarket notifications (K903152).

Device Description

Ethyl Alcohol Calibrators and Controls are aqueous phosphate buffer-based liquid, and ready to use. These Calibrators and Controls do not have any especially unique technical characteristics. Each contains a known concentration of ethanol.

The Negative Calibrator is a drug-free phosphate buffer matrix with preservative. The Ethyl Alcohol Calibrator (100 mg/dL) and Controls are prepared by spiking known concentrations of ethyl alcohol into the Negative Calibrator matrix. The various concentrations of ethyl alcohol in the calibrator and controls are summarized as follows:

	Ethyl Alcohol Assay
Material	Ethanol
Negative Calibrator	0 mg/dL
Calibrator	100 mg/dL
Control Level 1	45-55 mg/dL
Control Level 2	270-330 mg/dL

Intended Use

The Ethyl Alcohol Calibrators are intended for in vitro diagnostic use for the calibration of the Ethyl Alcohol Enzymatic Assay to measure ethyl alcohol in human urine, serum or plasma.
The Ethyl Alcohol Controls are intended for in vitro diagnostic use for the validation of the Ethyl Alcohol Enzymatic Assay to measure ethyl alcohol in human urine, serum or plasma.

Comparison to Predicate Device

LZI's Ethyl alcohol Calibrators and Controls are similar in intended use, matrix, and performance to the Syva's EMIT Ethyl Alcohol Calibrators and Controls.

Similarities:

- Both are for the calibration and validation of ethyl alcohol assay to measure ethyl alcohol in human urine, serum or plasma.
- Both assays use two point calibration, negative and 100 mg/dL calibrators.
- The nominal concentrations of the analyte in the calibrators and controls are determined and confirmed by GC/MS.
- Storage condition is the same, at 2°C to 8°C.

Conclusion

The information provided in the premarket notification demonstrates that the LZI's Ethyl Alcohol Calibrators and Controls are substantially equivalent to previously approved predicate devices, notably the Syva's EMIT Ethyl Alcohol Calibrators and Controls, 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 Ethyl Alcohol Enzymatic Assay. The reproducibility, description of the assay principle, and assay procedure can be found on the assay reagent package insert.

The following table illustrates the precision of calibrators and controls. Twelve vials each of calibrators and controls were used in the assay. 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 were collected on the Hitachi 717 Analyzer.

Ethyl Alcohol Enzymatic Assay:

(N = 12)	Neg. Cal	Calibrator
	negative	100 mg/dL
Ave. Rate (mA/min)	2.2	64.3
Stdev	0.21	4.00
%CV	9.44	0.22

(N =12)	Contl L_1	Contl L_2
	45-55 mg/mL	270-330 mg/dL
Ave. Conc. (mg/dL)	50.47	279.88
Stdev	2.30	8.26
% CV	4.56	2.95

Accuracy

The concentrations of the Ethyl Alcohol 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:

	Ethanol (mg/dL)	
	Expected	GC/MS
Calibrator	100	100
Level 1 Control	45-55	50
Level 2 Control	270-330	310

Ethanol was purchased from Sigma and Aldrich, St. Louis, MO 63178 (Traceable to NIST standard.).

Stability

The Ethyl Alcohol Calibrators and Controls were evaluated according to the following established procedures and criteria.

Procedure:

1. All Calibrators and controls were aliquoted and stored at either 2-8°C or Room temperature (RT).
2. Reagents of the EIA used were all stored at 2-8 °C.
3. At various time points, we evaluate the performance of the reagents using calibrators and controls stored at 2-8°C or RT, and comparing its performance (rate, mA/min.).

Stability Criteria:

1. The ratio of the enzyme rate from the RT-stored calibrators and controls vs. that of their respective 2-8°C-stored counter parts indicate the stability of the calibrators and controls.
2. A ratio of 1 (or 100%) indicated complete stability.
3. A ratio deviates from 1 for the negative (zero) calibrator would suggest instability of the buffer matrix.
4. Instability (decomposition or evaporation of the analyte, for example) of the drug of abuse in the non-zero calibrators and controls stored at higher temperature (RT vs. recommended 2-8°C) should result in substantial decrease in enzyme rates when tested with EIA reagents. Consistent decrease should occur for the same set of drug calibrators and controls.

Calibrators/controls stability data (in mA/min. unit)

Days	0	5		21		55		106		167	
mg/dL		Cold	RT	Cold	RT	Cold	RT	Cold	RT	Cold	RT
0	3.1	3.0	2.6	2.5	2.6	1.9	1.9	1.6	1.4	3.6	3.4
50	43.0	42.0	41.9	37.8	38.5	31.0	31.1	23.8	24.0	48.0	47.2
100	81.2	79.9	80.5	72.6	73.0	59.1	59.4	46.2	46.0	89.0	88.6
300	231.1	226.8	226.9	206.1	207.3	169.4	170.3	131.0	132.2	247.0	248.0

Note 1: The rate dropping is due to the reagent stability.
Note 2: Cold and RT rates are essentially the same.
Note 3: A new lot of reagent on day 167 was used. No difference between Cold and RT.

From the stability results, the calibrators and controls stored at RT performed equivalently to those stored at 2-8°C for at least 5 months (up to this writing). In other words, these calibrators and controls have shown 6 months RT stability. The calibrators used in this study were stored in a tightly capped 8-mL dropper type bottle with dropper tip and cap. Evaporation should not be a factor. At the present time, a recommended dating for 2-8°C storage is made for 12 month. Real time stability at refrigerated temperature is being continued.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 0 3 2003

Cheng-I Lin, Ph.D.
President
Lin-Zhi International, Inc.
687 North Pastoria Avenue
Sunnyvale, CA 94085

Re: k032461
Trade/Device Name: Ethyl Alcohol Enzymatic Assay, Calibrators and Controls
Regulation Number: 21 CFR 862.3040
Regulation Name: Alcohol test system
Regulatory Class: Class II
Product Code: DIC; DKC; DNN
Dated: August 6, 2003
Received: August 11, 2003

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 (301) 594-3084. 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/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): K032461

Device Name: Ethyl Alcohol Enzymatic Assay

Indications for Use:

The Ethyl Alcohol Enzymatic Assay is a homogeneous enzymatic assay with 0 and 100 mg/dL (0.1%) alcohol calibrators. The assay is intended for use in the quantitative analyses of ethyl alcohol in human urine, serum or plasma. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

Measurements obtained by this device are used in the diagnosis and treatment of alcohol intoxication and poisoning.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032461

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

Prescription Use (Per 21 CFR 801.109) **OR** **Over-The-Counter Use**

(Optional Format 1-2-96)

Premarket Notification Supplement

Indications for Use Statement

510(k) Number (if known): K032461

Device Name: **Ethyl Alcohol Calibrators and Controls**

Indications for Use:

The Ethyl Alcohol Calibrators are intended for in vitro diagnostic use for the calibration of the Ethyl Alcohol Enzymatic Assay to determine the ethyl alcohol concentration in human urine, serum or plasma.

The Ethyl Alcohol Controls are intended for in vitro diagnostic use for the validation of the Ethyl Alcohol Enzymatic Assay to determine ethyl alcohol in human urine, serum or plasma.

Jean Cooper

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032461

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

Prescription Use **OR** **Over-The-Counter Use**
(Per 21 CFR 801.109)

(Optional Format 1-2-96)