

SEP - 5 2003

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, R&D Director

Device Name and Classification

Classification Name: Benzodiazepine test system, Class II,
JMX (91 Toxicology),
21CFR 862.3170
Common Name: Homogeneous enzyme immunoassay for the determination of
Benzodiazepines levels in urine.
Proprietary Name: None

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.' Benzodiazepine Enzyme Immunoassay is substantially equivalent to Syva EMIT® II Plus Benzodiazepine Assay (By Syva Company-Dade Behring Inc.), cleared under premarket notification K993985.

LZI's Benzodiazepine Enzyme Immunoassay is identical or similar to its predicate in terms of intended use, method principle, device components, and clinical performance.

Device Description

LZI's Benzodiazepine Enzyme Immunoassay is a ready-to-use, liquid reagent, homogeneous enzyme immunoassay. The assay uses specific antibody that can detect benzodiazepines in human urine with minimal cross-reactivity to various, common prescription drugs and abused drugs.

The assay is based on competition between benzodiazepine labeled with glucose-6-phosphate dehydrogenase (G6PDH) enzyme and free drug from the urine sample for a fixed amount of specific antibody. In the absence of free drug from the urine 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 convert nicotinamide adenine dinucleotide (NAD) to NADH.

Intended Use

The Benzodiazepine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a 200 ng/mL and/or 300 ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analyses of benzodiazepines in human urine.

Comparison to Predicate Device

LZI's Benzodiazepine Enzyme Immunoassay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently, commercially marketed Emit® II Plus Benzodiazepine Assay (K993985) by Syva Company-Dade Behring Inc.

The following table compares LZI's Benzodiazepine Enzyme Immunoassay with the predicate device, Emit® II Plus Benzodiazepine Assay by Syva Company-Dade Behring Inc.

Similarities:

- Both assays are for qualitative and semi-quantitative determination of benzodiazepines in human urine.
- Both have dual cutoff design (200 ng/mL or 300 ng/mL).
- Both assays use 5 points calibration (0, 100, 200, 300, 1000 ng/ml) for semi-quantitative determination.
- Both assays use the same method principle, and device components.

Difference:

- Syva's assay uses 150, 225, 250, 375 ng/mL for various control levels. LZI's assay uses 100, 200, 300, 400 ng/mL for various control levels.
- Syva's assay uses lormetazepam as calibrator and control. LZI's assay uses oxazepam as calibrator and control.

Performance Characteristics

Feature	Syva's Benzodiazepine EIA				LZI's Benzodiazepine EIA			
Within Run Precision:								
Qualitative:	(mA/min.)	Mean.	SD	% CV	(mA/min.)	Mean	SD	% CV
	Negative	246.7	1.0	0.4	Negative	361.0	3.1	0.9
	150 ng/mL	294.7	1.2	0.4	100 ng/mL	417.8	3.5	0.8
	200 ng/mL	310.5	1.4	0.5	200 ng/mL	455.5	3.5	0.8
	225 ng/mL	319.3	1.3	0.4	300 ng/mL	483.3	3.5	0.7
	250 ng/mL	325.5	1.4	0.4	400 ng/mL	504.9	3.7	0.7
	300 ng/mL	336.1	1.4	0.4	1000 ng/mL	559.7	4.2	0.7
	375 ng/mL	349.7	2.4	0.7				
Semi-quantitative:	(ng/mL)	Mean	SD	%CV	(ng/mL)	Mean	SD	%CV
	150 ng/mL	148.2	3.3	2.2	100 ng/mL	105.7	7.6	7.2
	200 ng/mL	196.7	10.2	5.2	200 ng/mL	203.6	5.9	2.9
	225 ng/mL	225.1	4.5	2.0	300 ng/mL	281.8	11.1	3.9
	250 ng/mL	247.3	5.3	2.1	400 ng/ml	373.9	15.3	4.1
	300 ng/mL	289.5	5.9	2.0				
	375 ng/mL	353.8	6.2	1.8				
Run-To-Run Precision:								
Qualitative:	(mA/min.)	Mean	SD	% CV	(mA/min.)	Mean	SD	% CV
	Negative	246.7	1.7	0.7	Negative	360.0	2.5	0.7
	150 ng/mL	294.7	2.1	0.7	100 ng/mL	417.9	2.5	0.6
	200 ng/mL	310.5	2.2	0.7	200 ng/mL	457.0	1.9	0.4
	225 ng/mL	319.3	2.4	0.8	300 ng/mL	483.6	2.5	0.5
	250 ng/mL	325.5	2.3	0.7	400 ng/mL	504.4	2.8	0.6
	300 ng/mL	336.1	2.4	0.7	1000 ng/mL	561.8	3.3	0.6
	375 ng/mL	349.7	3.6	1.0				
Semi-quantitative:	(ng/mL)	Mean	SD	%CV	(ng/mL)	Mean	SD	%CV
	150 ng/mL	148.2	4.2	2.8	100 ng/mL	95.8	6.4	6.7
	200 ng/mL	196.7	11.0	5.6	200 ng/mL	192.0	6.5	3.4
	225 ng/mL	225.1	5.7	2.5	300 ng/mL	294.8	15.5	5.3
	250 ng/mL	247.3	5.7	2.3	400 ng/ml	398.6	15.4	3.9
	300 ng/mL	289.5	7.4	2.6				
	375 ng/mL	353.8	11.0	3.1				
Sensitivity:	15 ng/mL				15 ng/mL (functional)			
Accuracy:	Vs. a commercial EIA				Vs. Syva (n=116)			
Positive Samples:	95.6 % agreement				89.4 % agreement			
Negative Samples:	99% agreement				100 % agreement			
Analytical Recovery:								
Qualitative:	100 % accuracy on positive vs. negative tests							
Semi-quantitative:	Quantitates within $\pm 15\%$ of the nominal concentration between 40 ng/mL and 900 ng/mL.				Quantitates within $\pm 10\%$ of the nominal concentration between 20 ng/mL and 800 ng/mL.			
Specificity:	See attached Syva's Benzodiazepine Assay package insert				Comparable to the predicate device.			

Conclusion

LZI's Benzodiazepine Enzyme Immunoassay 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 Benzodiazepine Enzyme Immunoassay to other Benzodiazepine test systems currently marketed in the United States.



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Food and Drug Administration
2098 Gaither Road
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Cheng-I Lin, Ph.D.
President, R&D Director
Lin-Zhi International, Inc.
687 North Pastoria Avenue
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Re: k032365
Trade/Device Name: Benzodiazepine Enzyme Immunoassay
Regulation Number: 21 CFR 862.3170
Regulation Name: Benzodiazepine Test System
Regulatory Class: Class II
Product Code: JXM, DLJ, LAS
Dated: July 31, 2003
Received: July 31, 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.

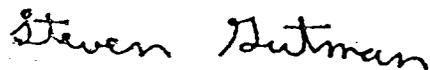
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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 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): K032365

Device Name: **Benzodiazepine Enzyme Immunoassay**

Indications for Use:

The Benzodiazepine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a 200 ng/mL and/or 300 ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analyses of benzodiazepines in human urine. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

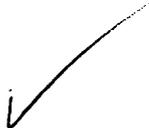
The Benzodiazepine Enzyme Immunoassay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when the preliminary positive results are used.


Division Sign-Off *for Jean Cooper*

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K032365

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): K032365

Device Name: Benzodiazepine Drug of Abuse Calibrators and Controls

Indications for Use:

The Benzodiazepine Drug of Abuse Calibrators are intended for in vitro diagnostic use for the calibration of the Benzodiazepine enzyme immunoassay to detect benzodiazepines in human urine.

The Benzodiazepine Drug of Abuse Controls are intended for in vitro diagnostic use for the validation of the Benzodiazepine enzyme immunoassay to detect benzodiazepines in human urine.

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)

Albert Souty
Division Sign-Off *for Jean Cooper*

Office of In Vitro Diagnostic Device
Evaluation and Safety

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