K020395

JUN 0 4 2002

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.
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San Jose, CA 95131-1124
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Contact: Chiu Chin Chang, Ph.D.
VP, R&D

Device Name and Classification

Classification Name:	Amphetamine test system, Class II, DKZ (91), 21 CFR 862.3100
Common Name:	Homogeneous enzyme immunoassay for the determination of amphetamines levels in urine.
Proprietary Name:	None

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.'s Amphetamines Enzyme Immunoassay is substantially equivalent to the Amphetamines Enzyme Immunoassay by Diagnostic Reagents Inc. (now Microgenics, Inc.), cleared under premarket notification K934891.

LZI's Amphetamines 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 Amphetamines Enzyme Immunoassay is a ready-to-use, liquid reagent, homogeneous enzyme immunoassay. The assay uses specific antibody that can detect amphetamine and/or methamphetamine in human urine with minimal cross-reactivity to other drugs of abuse, and common prescription drugs.

The assay is based on competition between amphetamines labeled with glucose-6-phosphate dehydrogenase (G6PDH) enzyme, and free drugs from the urine sample for a fixed amount of specific antibody mixtures. In the absence of free drugs from the urine sample the specific antibodies bind to the drugs labeled with G6PDH enzyme causing a decrease in 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 Amphetamines Enzyme Immunoassay is a homogeneous enzyme immunoassay with a 1000 ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analyses of amphetamines in human urine.

Comparison to Predicate Device

LZI's Amphetamines Enzyme Immunoassay is substantially equivalent to other products in commercially distribution intended for similar use. Most notably it is substantially equivalent to the currently, commercially marketed DRI's Amphetamines Enzyme Immunoassay (K934891).

The following table compares LZI's Amphetamines Enzyme Immunoassay with the predicate device, DRI's Amphetamines Enzyme Immunoassay:

Similarities:

- Both assays are for qualitative and semi-quantitative determination of amphetamines in human urine.
- Both assays use the same method principle, and device components.
- Both assay use 1000 ng/mL as cutoff level per recommendations of The Substance Abuse and Metal Health Services Administration (SAMHSA).

Differences:

LZI's Amphetamines Enzyme Immunoassay uses 5 calibrators for the semi-quantitative analysis of amphetamines in urine. DRI's Amphetamines EIA uses 3 calibrators for semi-quantitative purpose previously. Additional calibrators (to a total of 5 calibrators) are also available now.

(Comparison to Predicate Device, continued)

Performance Characteristics

Feature	DRI's Amphetamines EIA				LZI's Amphetamines EIA			
Within Run Precision:								
Qualitative:		Mean Rate	SD	% CV		Mean Rate	SD	% CV
	Negative	312	1	-	Negative	273.0	0.95	0.35
	750 ng/mL	418	2	-	750 ng/mL	390.0	1.45	0.37
	1000 ng/mL	443	2	-	1000 ng/mL	415.7	1.41	0.34
	1250 ng/mL	468	2	-	1250 ng/mL	439.0	1.63	0.37
	2000 ng/mL	513	3	-	2000 ng/mL	480.5	1.42	0.30
Semi-quantitative:	No data available					Mean Recovery	SD	% CV
					750 ng/mL	751.1	9.83	1.31
					1000 ng/mL	1008.6	14.02	1.39
					1250 ng/mL	1249.6	17.24	1.38
Run-To-Run Precision:								
Qualitative:	No data available					Mean Rate	SD	% CV
					Negative	272.9	2.28	0.84
					750 ng/mL	390.5	2.88	0.74
					1000 ng/mL	415.9	3.04	0.73
					1250 ng/mL	439.1	3.60	0.82
					2000 ng/mL	479.6	3.47	0.72
Semi-quantitative:	No data available					Mean Recovery	SD	% CV
					750 ng/mL	756.6	14.81	1.96
					1000 ng/mL	997.7	25.01	2.51
					1250 ng/mL	1265.2	29.54	2.33
Sensitivity:	10 ng/mL				30 ng/mL			
Accuracy:	Vs. a commercially available EIA				(1) Vs. DRI's Amphetamines EIA (n = 218)			
Positive Samples:	100 % agreement				100 % agreement			
Negative Samples:	100 % agreement				100 % agreement			
Analytical Recovery:								
Qualitative:	No data available				100 % accurate on positive vs. negative tests			
Semi-quantitative:	No data available				Quantitate within 10% of the nominal concentration between 300 ng/mL and 1900 ng/mL 104.2 % recovery at 750 ng/mL level (Cutoff - 25%) 101.2 % recovery at 1250 ng/mL level (Cutoff + 25%)			
Specificity:	See attached DRI's Amphetamines EIA package insert				Comparable to the predicate device.			

Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 0 4 2002

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Re: k020395
Trade/Device Name: Amphetamines Enzyme Immunoassay
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ
Dated: April 24, 2002
Received: April 26, 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 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 Part 801); 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.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification

Indications for Use Statement

510(k) Number (if known): K020395

Device Name: Amphetamines Enzyme Immunoassay

Indications for Use:

The Amphetamines Enzyme Immunoassay is a homogeneous enzyme immunoassay with a 1000 ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analyses of amphetamines in human urine.

The Amphetamines Enzyme Immunoassay 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.

Susan Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020395

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)