K023795

JAN 21 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.
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Contact: Chiu Chin Chang, Ph.D.
VP, R&D

Device Name and Classification

Classification Name:	Enzyme Immunoassay, Propoxyphene, Class II, JXN (91 Toxicology), 21CFR 862.3700
Common Name:	Homogeneous enzyme immunoassay for the determination of propoxyphene level in urine.
Proprietary Name:	None

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.' Propoxyphene Enzyme Immunoassay is substantially equivalent to the Propoxyphene Enzyme Immunoassay (By DRI/Microgenics Corp.), cleared under premarket notification K943414.

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

The assay is based on competition between propoxyphene 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 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 Propoxyphene Enzyme Immunoassay is a homogeneous enzyme immunoassay with a 300 ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analyses of propoxyphene in human urine.

Comparison to Predicate Device

LZI's Propoxyphene 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 Propoxyphene Enzyme Immunoassay (K943414) by Diagnostic Reagents, Inc. (DRI, now Microgenics Corporation)

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

Similarities:

- Both assays are for qualitative and semi-quantitative determination of propoxyphene in human urine.
- Both assays use the same method principle, and device components.
- Both assays use 300 ng/mL as cutoff level.

Differences:

- LZI's Propoxyphene Enzyme Immunoassay uses 5 calibrators for the semi-quantitative analysis of propoxyphene concentration in urine. DRI's Propoxyphene EIA used 3 calibrators previously. A total of 5 calibrators are available now from DRI in the "Multi-drug Urine Calibrators and Controls" product.

(Comparison to Predicate Device, continued)

Performance Characteristics

Feature	DRI's Propoxyphene EIA				LZI's Propoxyphene EIA			
Within Run Precision:								
Qualitative:		Mean Rate	SD	% CV		Mean Rate	SD	% CV
	Negative	153	-	1.1	Negative	117.4	0.5	0.47
	225 ng/mL	-	-	-	225 ng/mL	225.1	1.3	0.59
	300 ng/mL	265	-	1.0	300 ng/mL	261.3	1.6	0.61
	375 ng/mL	-	-	-	375 ng/mL	287.7	1.5	0.51
	1000 ng/mL	322	-	0.9	1000 ng/mL	350.0	1.4	0.39
Semi-quantitative:	No data available.					Mean Conc.	SD	% CV
					225 ng/mL	231.3	3.1	1.34
					300 ng/mL	299.6	5.8	1.92
					375 ng/mL	379.7	5.6	1.46
Run-To-Run Precision:								
Qualitative:		Mean Rate	SD	% CV		Mean Rate	SD	% CV
	Negative		154	1.0	Negative	116.8	1.0	0.88
	225 ng/mL		-	-	225 ng/mL	220.8	2.4	1.07
	300 ng/mL		265	0.8	300 ng/mL	255.9	2.1	0.81
	375 ng/mL		-	-	375 ng/mL	285.1	2.2	0.76
	1000 ng/mL		324	0.9	1000 ng/mL	349.5	1.9	0.55
Semi-quantitative:	No data available.					Mean Conc.	SD	% CV
					225 ng/mL	232.6	3.0	1.27
					300 ng/mL	298.7	4.7	1.56
					375 ng/mL	378.0	7.4	1.97
Sensitivity:	15 ng/mL				7.5 ng/mL			
Accuracy:	Vs. a commercial EIA: 116/126 in agreement All 57 positive samples by both assays were confirmed by GC/MS.				Vs. GC/MS 100 % agreement 100 % agreement			
Analytical Recovery:								
Qualitative:	No data available				100 % accuracy on positive vs. negative tests			
Semi-quantitative:	No data available				Quantitate within ±10% of the nominal concentration between 30 ng/mL and 900 ng/mL. Average 104.9 % recovery at 225 ng/mL level (Cutoff -25%) Average 103.8 % recovery at 375 ng/mL level (Cutoff + 25%)			
Specificity:	See attached DRI's Propoxyphene EIA package insert				Comparable to the predicate device.			

Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 21 2003

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Re: k023795
Trade/Device Name: Propoxyphene Enzyme Immunoassay
Regulation Number: 21 CFR 862.3700
Regulation Name: Propoxyphene test system
Regulatory Class: Class II
Product Code: JXN
Dated: November 11, 2002
Received: November 13, 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). 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): K023795

Device Name: Propoxyphene Enzyme Immunoassay

Indications for Use:

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

The Propoxyphene 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.

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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023795