K033885

MAY 1 9 2004

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: Cheng-I Lin, Ph.D.
President, R&D Director

Device Name and Classification

1. Classification Name: Barbiturate, Methadone, Benzodiazepine, and Propoxyphene test systems

The Barbiturate test system has been placed in Class II by the Bureau of Medical Devices.
Classification Number: DIS (21 CFR 862.3150)
Panel: 91 Toxicology

The Methadone test system has been placed in Class II by the Bureau of Medical Devices.
Classification Number: DJR (21 CFR 862.3620)
Panel: 91 Toxicology

The Benzodiazepine test system has been placed in Class II by the Bureau of Medical Devices.
Classification Number: JXM (21 CFR 862.3170)
Panel: 91 Toxicology

The Propoxyphene test system has been placed in Class II by the Bureau of Medical Devices.
Classification Number: JXN (21 CFR 862.3700)
Panel: 91 Toxicology

Common Name:	Homogeneous enzyme immunoassay for the detection of barbiturates, methadone, benzodiazepines, and propoxyphene in human urine.
Proprietary Name:	BMBP Enzyme Immunoassay

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.'s Simultaneous Barbiturate-Methadone-Benzodiazepine-Propoxyphene Multiple Analyte Enzyme Immunoassay is substantially equivalent to the individual Barbiturate Enzyme Immunoassay, Methadone Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, and Propoxyphene Enzyme Immunoassay by Lin-Zhi International, Inc., cleared under premarket notification K032764 (Barbiturate Enzyme Immunoassay), K023317 (Methadone Enzyme Immunoassay), K032365 (Benzodiazepine Enzyme Immunoassay), and K023795 (Propoxyphene Enzyme Immunoassay).

LZI's Simultaneous Barbiturate-Methadone-Benzodiazepine-Propoxyphene Multiple Analyte Enzyme Immunoassay is similar to their predicates in terms of intended use, method principle, device components, and clinical performance.

Device Description

LZI's Simultaneous Barbiturate-Methadone-Benzodiazepine-Propoxyphene Multiple Analyte Enzyme Immunoassay is a ready-to-use, liquid reagent, homogeneous enzyme immunoassay. The assay uses specific antibodies that can detect barbiturates, methadone, benzodiazepines, and propoxyphene drugs in human urine with minimal cross-reactivity to various, common prescription drugs and abused drugs.

The assay is based on competition between drug 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 Simultaneous Barbiturate-Methadone-Benzodiazepine-Propoxyphene Multiple Analyte Enzyme Immunoassay is a homogeneous enzyme immunoassay, with 200 ng/mL cutoff for secobarbital, 300 ng/mL cutoff for methadone, 200 ng/mL cutoff for oxazepam, and 300 ng/mL cutoff for propoxyphene. The assay is solely intended for use in the qualitative screening human urine samples for the presence of barbiturates, methadone, benzodiazepine, and propoxyphene drugs.

Comparison to Predicate Device

LZI's Simultaneous Barbiturate-Methadone-Benzodiazepine-Propoxyphene Multiple Analyte Enzyme Immunoassay is substantially equivalent to the individual single analyte assay products in commercially distribution intended for similar use. Most notably it is substantially equivalent to the Barbiturate Enzyme Immunoassay, Methadone Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, and Propoxyphene Enzyme Immunoassay by Lin-Zhi International, Inc., cleared under pre-market notification K032764 (Barbiturate Enzyme Immunoassay), K023317 (Methadone Enzyme Immunoassay), K032365 (Benzodiazepine Enzyme Immunoassay), and K023795 (Propoxyphene Enzyme Immunoassay).

The following table compares LZI's Simultaneous Barbiturate-Methadone-Benzodiazepine-Propoxyphene (BMBP) Multiple Analyte Enzyme Immunoassay with the predicate devices, Barbiturate Enzyme Immunoassay, Methadone Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, and Propoxyphene Enzyme Immunoassay by Lin-Zhi International, Inc.

Similarities:

- Both assays are used for qualitative detection of drug in human urine.
- Both have same cutoff design (200 ng/mL for secobarbital, 300 ng/mL for methadone, 200 ng/mL for oxazepam, and 300 ng/mL for propoxyphene).
- Both assays use same control concentration.
- Both assays use the same method principle, and device components.

Difference:

- Simultaneous Barbiturate-Methadone-Benzodiazepine-Propoxyphene Multiple Analyte Enzyme Immunoassay is designed for qualitative screening purpose only.
- The assay is for positive/negative screening only. Positive samples need further test to identify individual drug in the sample.
- Multiple analyte calibrators/controls cannot be use in this assay.
- Any single analyte calibrators and controls (secobarbital, methadone, oxazepam, or propoxyphene) can be used to verify and validate this assay.

Performance Characteristics

Feature	LZI's BMBP EIA				LZI's Barbiturate EIA			
Within Run Precision:	(mA/min.)	Mean.	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=21)	Negative	598.8	3.52	0.59	Negative	269.1	2.16	0.80
	100 ng/mL	625.2	5.53	0.88	100 ng/mL	311.1	1.92	0.62
	200 ng/mL	659.9	5.52	0.84	200 ng/mL	354.2	3.71	1.05
	300 ng/mL	679.2	5.47	0.81	300 ng/mL	385.1	3.07	0.80
	1000 ng/mL	722.9	3.79	0.52	1000 ng/mL	445.3	2.69	0.60
Run-To-Run Precision:	(mA/min.)	Mean	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=12)	Negative	600.0	5.31	0.88	Negative	271.1	2.3	0.83
	100 ng/mL	624.4	2.63	0.42	100 ng/mL	314.8	2.2	0.69
	200 ng/mL	653.3	4.18	0.64	200 ng/mL	359.0	1.9	0.53
	300 ng/mL	681.2	5.70	0.84	300 ng/mL	389.5	1.6	0.42
	1000 ng/mL	726.5	6.53	0.90	1000 ng/mL	447.4	1.6	0.35
Sensitivity:	50 ng/mL				25 ng/mL			
Accuracy:	Vs. LZI Barbiturate EIA				Vs. a commercial EIA			
Positive Samples:	100 % agreement				91.1 % agreement			
Negative Samples:	92.5 % agreement				100 % agreement			
Analytical Recovery:	100 % accuracy on positive vs. negative tests				100 % accuracy on positive vs. negative tests			
Specificity:	See attached Assay package insert				Comparable to the predicate device.			

Feature	LZI's BMBP EIA				LZI's Methadone EIA			
Within Run Precision:	(mA/min.)	Mean.	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=21)	Negative	596.3	4.27	0.72	Negative	209.4	1.0	0.49
	225 ng/mL	638.5	5.77	0.90	225 ng/mL	272.8	1.1	0.39
	300 ng/mL	657.3	3.80	0.58	300 ng/mL	293.4	0.7	0.25
	375 ng/mL	673.2	4.06	0.60	375 ng/mL	308.2	0.9	0.29
	1000 ng/mL	715.6	5.30	0.74	1000 ng/mL	344.9	1.1	0.33
Run-To-Run Precision:	(mA/min.)	Mean	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=12)	Negative	600.3	5.94	0.99	Negative	209.5	1.1	0.51
	225 ng/mL	640.0	5.45	0.85	225 ng/mL	271.4	2.0	0.74
	300 ng/mL	658.7	4.29	0.65	300 ng/mL	292.3	1.9	0.66
	375 ng/mL	673.3	5.30	0.79	375 ng/mL	307.2	2.6	0.84
	1000 ng/mL	707.3	5.00	0.71	1000 ng/mL	344.1	2.0	0.58
Sensitivity:	75 ng/mL				15 ng/mL			
Accuracy:	Vs. LZI Methadone EIA				Vs. a commercial EIA			
Positive Samples:	100 % agreement				100 % agreement (100% vs. GC/MS /HPLC)			
Negative Samples:	95.0 % agreement				100 % agreement			
Analytical Recovery:	100 % accuracy on positive vs. negative tests				100 % accuracy on positive vs. negative tests			
Specificity:	See attached Assay package insert				Comparable to the predicate device.			

Feature	LZI's BMBP EIA				LZI's Benzodiazepine EIA			
Within Run Precision:	(mA/min.)	Mean.	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=21)	Negative	602.1	3.8	0.64	Negative	361.0	3.1	0.86
	100 ng/mL	635.7	3.6	0.56	100 ng/mL	417.8	3.5	0.84
	200 ng/mL	655.9	4.5	0.68	200 ng/mL	455.5	3.5	0.76
	300 ng/mL	683.7	4.6	0.68	300 ng/mL	483.3	3.5	0.73
	1000 ng/mL	736.1	5.5	0.75	1000 ng/mL	559.7	4.9	0.74
Run-To-Run Precision:	(mA/min.)	Mean	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=12)	Negative	600.8	5.0	0.83	Negative	360.0	2.5	0.70
	100 ng/mL	637.6	4.2	0.66	100 ng/mL	417.9	2.5	4.42
	200 ng/mL	655.6	4.5	0.69	200 ng/mL	457.0	1.9	0.51
	300 ng/mL	683.0	5.3	0.78	300 ng/mL	483.6	2.4	0.55
	1000 ng/mL	739.0	7.0	0.95	1000 ng/mL	561.8	3.3	0.58
Sensitivity:	25 ng/mL				15 ng/mL			
Accuracy:	Vs. LZI Benzodiazepine EIA				Vs. a commercial EIA			
Positive Samples:	100 % agreement				96.9 % agreement(vs. GC/MS /HPLC)			
Negative Samples:	97.5 % agreement				84 % agreement			
Analytical Recovery:	100 % accuracy on positive vs. negative tests				100 % accuracy on positive vs. negative tests			
Specificity:	See attached Assay package insert				Comparable to the predicate device.			

Feature	LZI's BMBP EIA				LZI's Propoxyphene EIA			
Within Run Precision:	(mA/min.)	Mean.	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=21)	Negative	600.5	5.19	0.86	Negative	117.4	0.5	0.47
	225 ng/mL	642.5	5.48	0.85	225 ng/mL	225.1	1.3	0.59
	300 ng/mL	656.8	5.54	0.84	300 ng/mL	261.3	1.6	0.61
	375 ng/mL	671.8	4.84	0.72	375 ng/mL	287.7	1.5	0.51
	1000 ng/mL	702.5	5.30	0.75	1000 ng/mL	350.0	1.4	0.39
Run-To-Run Precision:	(mA/min.)	Mean	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=12)	Negative	599.5	4.2	0.70	Negative	116.8	1.0	0.88
	225 ng/mL	642.1	4.3	0.67	225 ng/mL	220.8	2.4	1.07
	300 ng/mL	657.7	4.8	0.73	300 ng/mL	255.9	2.1	0.81
	375 ng/mL	671.4	6.3	0.94	375 ng/mL	285.1	2.2	0.76
	1000 ng/mL	707.5	2.5	0.35	1000 ng/mL	349.5	1.9	0.55
Sensitivity:	50 ng/mL				15 ng/mL			
Accuracy:	Vs. LZI Propoxyphene EIA				Vs. a commercial EIA			
Positive Samples:	100 % agreement				100 % agreement(vs. GC/MS /HPLC)			
Negative Samples:	97.5 % agreement				100 % agreement			
Analytical Recovery:	100 % accuracy on positive vs. negative tests				100 % accuracy on positive vs. negative tests			
Specificity:	See attached Assay package insert				Comparable to the predicate device.			

Conclusion

The LZI's Simultaneous Barbiturate-Methadone-Benzodiazepine-Propoxyphene Multiple Analyte 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 individual 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 Simultaneous Barbiturate-Methadone-Benzodiazepine-Propoxyphene Multiple Analyte Enzyme Immunoassay to other individual test systems for screening purpose currently marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 19 2004

Cheng-I Lin, Ph.D.
President
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687 North Pastoria Avenue
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Re: k033885
Trade/Device Name: Simultaneous Barbiturate- Methadone-Benzodiazepine Propoxyphene(BMBP) Multiple Analyte Enzyme Immunoassay
Regulation Number: 21 CFR 862.3150
Regulation Name: Barbiturate test system
Regulatory Class: Class II
Product Code: DIS, DJR, JXM, JXN
Dated: April 21, 2004
Received: April 27, 2004

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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K033885

Device Name: Simultaneous Barbiturate-Methadone-Benzodiazepine-Propoxyphene (BMBP) Multiple Analyte Enzyme Immunoassay

Indications for Use:

The Simultaneous Barbiturate-Methadone-Benzodiazepine-Propoxyphene (BMBP) Multiple Analyte Enzyme Immunoassay is a homogeneous enzyme immunoassay. The assay is solely intended for use in the qualitative screening human urine samples for the presence of barbiturates, methadone, benzodiazepines, and propoxyphene drugs. . The assay will produce a positive result if any of the four analyte are present at a concentration at or above their respective cutoffs but will not identify which drug is present. The assay is solely intended for the qualitative screening of human urine for these analytes. Measurements obtained by this device are used in the diagnosis and treatment of individuals who have used barbiturates, methadone, benzodiazepines, and propoxyphene drugs. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

The Simultaneous Barbiturate-Methadone-Benzodiazepine-Propoxyphene Multiple Analyte Enzyme Immunoassay provides only a preliminary analytical test result. The assay will not identify which drug is present in the positive urine sample. All screening positive samples shall subject to individual assays to identify the drug in the sample before alternative confirmation. 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 preliminary positive results are used.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033885

Prescription Use V **AND/OR** **Over-The-Counter Use** _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of IN Vitro Diagnostic Device (OIVD)