AUG 1 5 2002

K021887

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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San Jose, CA 95131-1124
Phone: (408) 944-0360
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Contact: Chiu Chin Chang, Ph.D.
VP, R&D

Device Name and Classification

Classification Name:	Enzyme Immunoassay, Cannabinoids, Class II, LDJ (91 Toxicology), 21CFR 862.3870
Common Name:	Homogeneous enzyme immunoassay for the determination of cannabinoids (THC) level in urine.
Proprietary Name:	None

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.'s Cannabinoid Enzyme Immunoassay is substantially equivalent to the Cannabinoid (THC) Enzyme Immunoassay (By DRI/Microgenics Corp.), cleared under premarket notification K943998.

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

The assay is based on competition between Δ^9-THC-labeled 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 Cannabinoid Enzyme Immunoassay is a homogeneous enzyme immunoassay with a 20 ng/mL, 50 ng/mL (SAMHSA recommended initial test cutoff concentration), or 100 ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analyses of cannabinoids (THC) in human urine. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

Comparison to Predicate Device

LZI's Cannabinoid 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 Cannabinoid (THC) Enzyme Immunoassay (K943998) by Diagnostic Reagents, Inc. (DRI, now Microgenics Corporation)

The following table compares LZI's Cannabinoid Enzyme Immunoassay with the predicate device, DRI's Cannabinoid (THC) Enzyme Immunoassay.

Similarities:

- Both assays are for qualitative and semi-quantitative determination of cannabinoids in human urine.
- Both assays use the same method principle, and device components.
- Both assays can be used with a 20 ng/mL, 50 ng/mL (Cutoff level per recommendations of The Substance Abuse and Metal Health Services Administration, or SAMHSA), or 100 ng/mL cutoff.
- The same 5 calibrators were used for qualitative analyses of the assay.

Differences:

- In the semi-quantitative analysis of cannabinoids concentration in urine, LZI's Cannabinoid Enzyme Immunoassay uses a specified 5 calibrators set for each cutoff assay. DRI's Cannabinoid (THC) EIA used the same 5 calibrators for both qualitative analyses and the semi-quantitative analyses purposes.

(Comparison to Predicate Device, continued)

Performance Characteristics

Feature	DRI's Cannabinoid (THC) EIA				LZI's Cannabinoid EIA			
Within Run Precision:					(Illustrated with THC 50 assay results)			
Qualitative:		Mean Rate	SD	% CV		Mean Rate	SD	% CV
	Negative	287	-	1.0	Negative	318.7	2.2	0.68
	20 ng/mL	317	-	0.9	20 ng/mL	346.3	2.5	0.72
	50 ng/mL	387	-	0.9	50 ng/mL	398.7	3.5	0.87
	100 ng/mL	447	-	0.9	100 ng/mL	456.0	3.3	0.73
	200 ng/mL	472	-	0.5	200 ng/mL	475.1	1.9	0.39
Semi-quantitative:	No data available.					Mean Conc	SD	% CV
					37.5 ng/mL	38.3	0.8	2.12
					50 ng/mL	50.0	1.4	2.78
					62.5 ng/mL	65.1	1.9	2.91
Run-To-Run Precision:					(Illustrated with THC 50 assay results)			
Qualitative:		Mean Rate	SD	% CV		Mean Rate	SD	% CV
	Negative	287	-	1.0	Negative	320.5	3.1	0.96
	20 ng/mL	319	-	0.7	20 ng/mL	347.6	2.3	0.66
	50 ng/mL	388	-	1.0	50 ng/mL	399.8	3.9	0.97
	100 ng/mL	449	-	1.2	100 ng/mL	457.6	4.0	0.88
	200 ng/mL	473	-	0.8	200 ng/mL	477.1	3.5	0.73
Semi-quantitative:	No data available.					Mean Conc	SD	% CV
					37.5 ng/mL	37.1	0.9	2.41
					50 ng/mL	48.4	1.5	3.02
					62.5 ng/mL	63.9	2.3	3.59
Sensitivity:	10 ng/mL				5 ng/mL (THC 20 assay); 7.5 ng/mL (THC 50 assay); 15 ng/mL (THC 100 assay)			
Accuracy:	Vs. GC/MS* (n = 592)				Vs. DRI's Cannabinoid EIA (n = 216)			
	THC 20 assay	THC 50 assay	THC 100 assay		THC 20 assay	THC 50 assay	THC 100 assay	
Positive Samples:	No data	100% Agreement	6 borderline negative found		100 % Agreement	100 % Agreement	98.3 % (1 marginal discrepant)	
Negative Samples:	No data	100% Agreement	100% Agreement		100 % Agreement	100 % Agreement	100 % Agreement	
Analytical Recovery:					(Illustrated with THC 50 assay)			
Qualitative:	No data available				100 % accuracy on positive vs. negative tests			
Semi-quantitative:	No data available				Quantitate within ±12% of the nominal concentration between 10 ng/mL and 95 ng/mL. Average 98.7 % recovery at 37.5 ng/mL level (Cutoff - 25%) Average 93.2 % recovery at 62.5 ng/mL level (Cutoff + 25%)			
Specificity:	See attached DRI's Cannabinoid (THC) EIA package insert				Comparable to the predicate device.			

* A 15 ng/mL cutoff for GC/MS was used for comparison.

Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 15 2002

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Re: k021887
Trade/Device Name: Cannabinoid Enzyme Immunoassay
Regulation Number: 21 CFR 862. 3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: LDJ
Dated: June 5, 2002
Received: June 7, 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): K021887

Device Name: Cannabinoid Enzyme Immunoassay

Indications for Use:

The Cannabinoid Enzyme Immunoassay is a homogeneous enzyme immunoassay with a 20 ng/mL, 50 ng/mL (SHAHSA recommended initial test cutoff concentration), or 100 ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analyses of cannabinoids (THC) in human urine. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

The Cannabinoid 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.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021887

Concurrence of CDRH, Office of Device Evaluation (ODE)

X

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

(Optional Format 1-2-96)