DEC 22 2008

510(k) Summary of Safety and Effectiveness K083008

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
Email: mtlin@lin-zhi.com

Contact: Marie Lin, Ph.D.
President, R&D Director

Device Name and Classification

Classification Name:	Enzyme immunoassay, Opiates Class II, DJG (91 Toxicology), 21 CFR 862.3650
	Norbuprenorphine calibrators, Class II, DLJ (91 Toxicology), 21 CFR 862.3200
	Norbuprenorphine controls, Class I, LAS (91 Toxicology), 21 CFR 862.3280
Common Name:	Homogeneous Buprenorphine Enzyme Immunoassay
Proprietary Name:	LZI Buprenorphine Enzyme Immunoassay, Calibrators and Controls: for Beckman Coulter® Synchron Systems

Legally Marketed Predicate Device(s)

The LZI Buprenorphine Enzyme Immunoassay (EIA) is substantially equivalent to the CEDIA® Buprenorphine Assay (K040316) manufactured by Microgenics Corporation. LZI's Buprenorphine Enzyme Immunoassay is identical or similar to its predicate in terms of intended use, method principle, device components, and clinical performance.

Device Description

The LZI Buprenorphine assay is a homogeneous enzyme immunoassay with ready-to-use liquid reagent. The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for a fixed amount of antibody in the reagent. Enzyme activity decreases upon binding to the antibody, and the drug concentration in the sample is measured in terms of enzyme activity. In the absence of drug in the sample, buprenorphine-labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. On the other hand, when free drug is present in the sample, antibody would bind to free drug, the unbound buprenorphine-labeled G6PDH then exhibits its maximal enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that can be measured spectrophotometrically at 340 nm

Intended Use

The Lin-Zhi International (LZI) Buprenorphine Enzyme Immunoassay, when used in conjunction with Beckman Coulter® Synchron LX®, CX®, and UniCel® DxC automated clinical system analyzers, is intended for the qualitative and semi-quantitative determination of norbuprenorphine (buprenorphine metabolite) in human urine, at a cutoff value of 10 ng/mL.

The Norbuprenorphine Drugs of Abuse (DAU) Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the Lin-Zhi International (LZI) Buprenorphine Enzyme Immunoassay with Beckman Coulter® Synchron LX®, CX®, and UniCel® DxC automated clinical system analyzers.

The Norbuprenorphine Drugs of Abuse (DAU) Controls are for use as assayed quality control materials to monitor the precision of the Lin-Zhi International (LZI) Buprenorphine Enzyme Immunoassay with Beckman Coulter® Synchron LX®, CX®, and UniCel® DxC automated clinical system analyzers.

The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method (1,2). Clinical consideration and professional judgement should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

Comparison to Predicate Device

The LZI Buprenorphine Enzyme Immunoassay is substantially equivalent to the CEDIA® Buprenorphine Assay (by Microgenics Corporation), cleared by the FDA under the premarket notification K040316 for its stated intended use.

The following table compares LZI's Buprenorphine Enzyme Immunoassay with the predicate device, CEDIA® Buprenorphine Assay by Microgenics Corporation.

Device Characteristics	**Subject Device** LZI Buprenorphine Enzyme Immunoassay for Beckman Coulter® Synchron Systems	**Predicate Device** CEDIA® Buprenorphine Assay (K040316)
Intended Use	The Lin-Zhi International (LZI) Buprenorphine Enzyme Immunoassay, when used in conjunction with Beckman Coulter® Synchron LX®, CX®, and UniCel® DxC automated clinical system analyzers, is intended for the qualitative and semi-quantitative determination of norbuprenorphine (buprenorphine metabolite) in human urine, at a cutoff value of 10 ng/mL. ***This assay provides a rapid screening procedure for determining the presence of norbuprenorphine (buprenorphine metabolite) in urine. The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method (1,2). Clinical consideration and professional judgement should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.***	The CEDIA Buprenorphine assay is a homogeneous enzyme immunoassay for qualitative or semi-quantitative determination of the presence of buprenorphine in human urine at cutoff concentration of 5 ng/mL. The assay provides a simple and rapid analytical screening procedure to detect buprenorphine in human urine. ***The assay provides only a preliminary analytical 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 and professional judgement should be applied to any drug of abuse test result, particularly when preliminary results are used.***
Analyte	Norbuprenorphine (buprenorphine metabolite)	Buprenorphine
Cutoff	10 ng/ml	5 ng/ml
Matrix	Urine	Urine
Calibrators Level	6 Levels (0, 5, 10, 20, 40, 100 ng/mL)	5 Levels (0, 5, 20, 50 and 75 ng/ml)
Controls Level	2 Levels (7 ng/mL, 13 ng/mL)	2 Levels (3 ng/mL, 7 ng/mL)
Storage	2-8°C until expiration date	2-8°C until expiration date

Performance Characteristics Summary:

Precision: Semi-Quantitative, ng/mL

CX4CE Analyzer:

Drug: Norbuprenorphine	Sample concentration, ng/mL	Mean, ng/mL	SD	CV%		Mean, ng/mL	SD	CV%
	Within-Run (n=21)				Run-to-Run (n=20 over 2 weeks)			
Norbuprenorphine	0	0.0	0.0	0.0	0	0.0	0.1	n/a
Norbuprenorphine	2.5	3.4	0.4	11.2	2.5	3.0	0.4	14.9
Norbuprenorphine	5.0	5.9	0.5	7.9	5.0	5.9	0.4	6.3
Norbuprenorphine	7.5	7.7	0.3	3.9	7.5	7.9	0.5	6.2
Norbuprenorphine	10.0	10.2	0.4	3.5	10.0	10.2	0.5	4.5
Norbuprenorphine	12.5	12.7	0.5	3.7	12.5	12.7	0.3	2.7
Norbuprenorphine	15.0	15.1	0.4	2.4	15.0	15.3	0.6	3.8
Norbuprenorphine	17.5	17.4	0.7	3.8	17.5	17.8	0.4	2.4
Norbuprenorphine	20.0	20.5	0.6	2.9	20.0	20.8	0.6	2.9

LX20 Pro Analyzer:

Drug: Norbuprenorphine	Sample concentration, ng/mL	Mean, ng/mL	SD	CV%		Mean, ng/mL	SD	CV%
	Within-Run (n=21)				Run-to-Run (n=20 over 2 weeks)			
Norbuprenorphine	0	0.0	0.1	n/a	0	0.1	0.3	242.2
Norbuprenorphine	2.5	3.6	0.4	9.8	2.5	3.2	0.7	22.6
Norbuprenorphine	5.0	5.5	0.7	13.1	5.0	5.8	0.5	9.3
Norbuprenorphine	7.5	8.1	0.2	2.7	7.5	7.9	0.6	7.3
Norbuprenorphine	10.0	10.7	0.2	2.1	10.0	10.5	0.6	5.6
Norbuprenorphine	12.5	12.8	0.5	3.9	12.5	12.8	0.5	4.1
Norbuprenorphine	15.0	15.2	0.5	3.3	15.0	14.9	0.7	4.4
Norbuprenorphine	17.5	18.6	0.5	2.9	17.5	17.8	0.7	4.0
Norbuprenorphine	20.0	21.0	0.5	2.3	20.0	20.6	1.0	4.6

DxC600 Analyzer:

Drug: Norbuprenorphine	Sample concentration, ng/mL	Mean, ng/mL	SD	CV%		Mean, ng/mL	SD	CV%
	Within-Run (n=21)				Run-to-Run (n=20 over 2 weeks)			
Norbuprenorphine	0	0.0	0.0	0.0	0	0.2	0.4	162.1
Norbuprenorphine	2.5	3.2	0.5	16.4	2.5	3.2	0.3	10.0
Norbuprenorphine	5.0	6.1	0.3	5.1	5.0	6.0	0.3	4.8
Norbuprenorphine	7.5	7.9	0.2	2.5	7.5	7.7	0.3	3.4
Norbuprenorphine	10.0	10.4	0.4	4.2	10.0	10.0	0.3	3.4
Norbuprenorphine	12.5	12.6	0.4	3.4	12.5	12.1	0.3	2.2
Norbuprenorphine	15.0	14.9	0.4	2.4	15.0	14.6	0.4	2.6
Norbuprenorphine	17.5	17.6	0.5	2.9	17.5	17.3	0.5	2.9
Norbuprenorphine	20.0	20.2	0.5	2.5	20.0	20.0	0.4	2.0

Precision: Qualitative, mA/min

CX4CE Analyzer:

Drug: Norbuprenorphine	Sample concentration, ng/mL	Mean, mA/min	SD	CV%		Mean, mA/min	SD	CV%
	Within-Run (n=21)				Run-to-Run (n=20 over 2 weeks)			
Norbuprenorphine	0	367.4	1.7	0.5	0	366.8	1.9	0.5
Norbuprenorphine	2.5	379.4	1.4	0.4	2.5	378.5	1.5	0.4
Norbuprenorphine	5.0	389.8	2.1	0.5	5.0	390.8	1.0	0.2
Norbuprenorphine	7.5	398.8	1.5	0.4	7.5	400.2	1.8	0.5
Norbuprenorphine	10.0	411.2	1.8	0.4	10.0	412.3	1.7	0.4
Norbuprenorphine	12.5	424.6	2.4	0.6	12.5	425.3	1.6	0.4
Norbuprenorphine	15.0	437.1	1.9	0.4	15.0	438.6	2.0	0.5
Norbuprenorphine	17.5	448.6	3.3	0.7	17.5	451.3	2.1	0.5
Norbuprenorphine	20.0	463.6	2.8	0.6	20.0	465.4	2.2	0.5

LX20 Pro Analyzer:

Drug: Norbuprenorphine	Sample concentration, ng/mL	Mean, mA/min	SD	CV%		Mean, mA/min	SD	CV%
	Within-Run (n=21)				Run-to-Run (n=20 over 2 weeks)			
Norbuprenorphine	0	368.2	1.8	0.5	0	371.7	3.7	1.0
Norbuprenorphine	2.5	385.8	2.1	0.5	2.5	386.2	3.4	0.9
Norbuprenorphine	5.0	398.0	4.9	1.2	5.0	401.6	3.0	0.7
Norbuprenorphine	7.5	417.8	1.7	0.4	7.5	414.9	3.5	0.8
Norbuprenorphine	10.0	437.6	1.7	0.4	10.0	433.7	2.7	0.6
Norbuprenorphine	12.5	452.7	3.5	0.8	12.5	450.2	2.4	0.5
Norbuprenorphine	15.0	469.1	3.3	0.7	15.0	465.0	2.8	0.6
Norbuprenorphine	17.5	490.3	3.1	0.6	17.5	482.9	3.1	0.6
Norbuprenorphine	20.0	503.3	2.5	0.5	20.0	498.5	4.0	0.8

DxC600 Analyzer:

Drug: Norbuprenorphine	Sample concentration, ng/mL	Mean, mA/min	SD	CV%		Mean, mA/min	SD	CV%
	Within-Run (n=21)				Run-to-Run (n=20 over 2 weeks)			
Norbuprenorphine	0	378.7	2.4	0.6	0	384.9	3.3	8.6
Norbuprenorphine	2.5	395.1	2.9	0.7	2.5	397.6	2.5	6.3
Norbuprenorphine	5.0	414.6	2.4	0.6	5.0	415.4	2.4	5.7
Norbuprenorphine	7.5	428.4	1.6	0.4	7.5	428.5	2.4	5.7
Norbuprenorphine	10.0	449.1	3.6	0.8	10.0	446.6	2.0	4.6
Norbuprenorphine	12.5	467.5	3.4	0.7	12.5	463.6	1.5	3.3
Norbuprenorphine	15.0	484.9	2.6	0.5	15.0	481.4	2.4	5.0
Norbuprenorphine	17.5	503.3	3.2	0.6	17.5	499.9	2.2	4.4
Norbuprenorphine	20.0	518.7	2.9	0.6	20.0	515.6	2.2	4.3

Precision: Qualitative, Positive/Negative

CX4CE Analyzer		Within Run		Run to Run	
Sample [ ], ng/mL	% of Cutoff	# of Determination	Result	# of Determination	Result
0	- 100%	21	21 NEG	20	20 NEG
2.5	- 75%	21	21 NEG	20	20 NEG
5.0	- 50%	21	21 NEG	20	20 NEG
7.5	- 25%	21	21 NEG	20	20 NEG
10.0	100%	21	13 POS/8 NEG	20	12 POS/8 NEG
12.5	+ 25%	21	21 POS	20	20 POS
15.0	+ 50%	21	21 POS	20	20 POS
17.5	+ 175%	21	21 POS	20	20 POS
20.0	+ 200%	21	21 POS	20	20 POS

LX20 Pro Analyzer		Within Run		Run to Run	
Sample [ ], ng/mL	% of Cutoff	# of Determination	Result	# of Determination	Result
0	- 100%	21	21 NEG	20	20 NEG
2.5	- 75%	21	21 NEG	20	20 NEG
5.0	- 50%	21	21 NEG	20	20 NEG
7.5	- 25%	21	21 NEG	20	20 NEG
10.0	100%	21	21 POS	20	20 POS
12.5	+ 25%	21	21 POS	20	20 POS
15.0	+ 50%	21	21 POS	20	20 POS
17.5	+ 175%	21	21 POS	20	20 POS
20.0	+ 200%	21	21 POS	20	20 POS

DxC600 Analyzer		Within Run		Run to Run	
Sample [ ], ng/mL	% of Cutoff	# of Determination	Result	# of Determination	Result
0	- 100%	21	21 NEG	20	20 NEG
2.5	- 75%	21	21 NEG	20	20 NEG
5.0	- 50%	21	21 NEG	20	20 NEG
7.5	- 25%	21	21 NEG	20	20 NEG
10.0	100%	21	18 POS/3 NEG	20	13 POS/7 NEG
12.5	+ 25%	21	21 POS	20	20 POS
15.0	+ 50%	21	21 POS	20	20 POS
17.5	+ 175%	21	21 POS	20	20 POS
20.0	+ 200%	21	21 POS	20	20 POS

Detection Limit:
The lowest concentration that can be differentiated from the negative urine with 95% confidence is determined as 3 ng/mL on all three platforms of instruments.

Linearity:
CX4CE Instrument: 3-90 ng/mL
LX20 Pro Instrument: 3-70 ng/mL
DxC Instrument: 3-70 ng/mL

Method comparison against GC/MS confirmation device:
CX4CE Instrument: 83 clinical unaltered samples, 93.0% agreement with positive, 97.5% agreement with negative samples)

LX20 Pro Instrument: 82 clinical unaltered samples, 97.4% agreement with positive, 95.3% agreement with negative samples)

DxC Instrument: 83 clinical unaltered samples, 97.4% agreement with positive, 95.3% agreement with negative samples)

Specificity and Endogenous Substances:
No significant undesired cross reactants or endogenous substance interference were observed. See product insert for list of compounds tested.

Summary:

The information provided in this pre-market notification demonstrates that the LZI Buprenorphine Enzyme Immunoassay is substantially equivalent to the legally marketed predicated device for its general intended use. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available predicate device as confirmed by gas chromatography/mass spectrometry, an independent analytical method. The information supplied in this pre-market notification provides reasonable assurance that the LZI Buprenorphine Enzyme Immunoassay is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Lin-Zhi International, Inc.
c/o Marie Lin
President
687 North Pastoria Ave
Sunnyvale, CA 94085

DEC 22 2008

Re: k081008
Trade/Device Name: Buprenorphine Enzyme Immunoassay and Norbuprenorphine Calibrators and Controls

Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG, DLJ and LAS
Dated: November 05, 2008
Received: November 07, 2008

Dear Ms. 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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., 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

Premarket Notification

Indications for Use Statement

510(k) Number (if known): k081008

Device Name: **Buprenorphine Enzyme Immunoassay and Calibrators and Controls.**
for Beckman Coulter® Synchron Systems

Indications For Use:

The Lin-Zhi International (LZI) Buprenorphine Enzyme Immunoassay, when used in conjunction with Beckman Coulter® Synchron LX®, CX®, and UniCel® DxC automated clinical system analyzers, is intended for the qualitative and semi-quantitative determination of norbuprenorphine (buprenorphine metabolite) in human urine, at a cutoff value of 10 ng/mL.

The Norbuprenorphine Drugs of Abuse (DAU) Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the Lin-Zhi International (LZI) Buprenorphine Enzyme Immunoassay with Beckman Coulter® Synchron LX®, CX®, and UniCel® DxC automated clinical system analyzers.

The Norbuprenorphine Drugs of Abuse (DAU) Controls are for use as assayed quality control materials to monitor the precision of the Lin-Zhi International (LZI) Buprenorphine Enzyme Immunoassay with Beckman Coulter® Synchron LX®, CX®, and UniCel® DxC automated clinical system analyzers.

The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method). Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
(Part 21 CFR 801.109)

Division of Clinical Laboratory Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

k081008