JUN 13 2005

K050733

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

Classification Name: Enzyme Immunoassay, Opiate
Class II, DJG (91 Toxicology),
21CFR 862.3650

Oxycodone calibrators,
Class II, DLJ, (91 Toxicology),
21CFR 862.3200

Oxycodone controls,
Class I, LAS (91 Toxicology),
21CFR 862.3280

Common Name: Homogeneous Oxycodone Enzyme Immunoassay
Proprietary Name: LZI Oxycodone Assay

Legally Marketed Predicate Device(s)

The LZI Oxycodone Enzyme Immunoassay is substantially equivalent to the DRI® Oxycodone Assay (K040411) manufactured by DRI/Microgenics Corp.

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

The assay is based on competition between oxycodone derivative labeled with glucose-6-phosphate dehydrogenase (G6PDH) enzyme and free drug from sample for a fixed amount of specific antibody. In the absence of free drug from the 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 covert nicotinamide adenine dinucleotide (NAD) to NADH.

Intended Use

The LZI Oxycodone Enzyme Immunoassay is a homogeneous enzyme immunoassay with 100 and 300 ng/mL cutoffs. The assay is intended for use in the qualitative and semi-quantitative analyses of oxycodone and its metabolite in human urine.
The LZI Oxycodone 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 judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

Comparison to Predicate Device

LZI's Oxycodone Enzyme Immunoassay is substantially equivalent to the product in commercially distribution intended for similar use. Most notably it is substantially equivalent to the currently, commercially marketed DRI® Oxycodone Assay (K040411) by Microgenics Corporation.

The following table compares LZI's Oxycodone Enzyme Immunoassay with the predicate device, DRI Oxycodone Enzyme Immunoassay by Microgenics Corp.

Similarities:

- Both assays are for qualitative and semi-quantitative determination of oxycodone and its metabolite in human urine.
- Both are ready-to-use liquid reagents.
- Both have 100 and 300 ng/mL cutoffs.
- Both assays use the same method principle, and device components.
- Both stored at 2°C to 8°C until expiration date.

Differences:

- DRI assay uses 5 points calibration (0, 100, 300, 500, 1000 ng/ml) for semi-quantitative determination. LZI assay uses three different calibrator/control sets (0, 75, 100, 225, and 300 ng/mL) (0, 100, 300, 500 and 800 ng/mL) for semi-quantitative determination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 13 2005

Cheng-I Lin, Ph.D.
President
Lin-Zhi International, Inc.
687 North Pastoria Ave
Sunnyvale, CA 94085

Re: k050733
Trade/Device Name: Oxycodone Enzyme Immunoassay and Oxyodone Calibrators and Controls
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG, DLJ, LAS
Dated: May 20, 2005
Received: May 24, 2005

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting 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): K050733

Device Name: Oxycodone Enzyme Immunoassay and Oxycodone Calibrators and Controls.

Indications for Use:

The Oxycodone Enzyme Immunoassay is a homogeneous enzyme immunoassay with 100 and 300 ng/mL cutoffs. The assay is intended for use in the qualitative and semi-quantitative analyses of oxycodone and its metabolite, oxymorphone in human urine.
The Oxycodone calibrators are used to calibrate the oxycodone enzyme immunoassay for drug detection in human urine. The Oxycodone controls are used to validate the assay.
The assay provides a simple and rapid analytical screening procedure to detect oxycodone and its metabolite in human urine.
The assay is designed for professional use with a number of automated clinical chemistry analyzers. Performance data submitted was obtained using the Hitachi 717 analyzer.
The Oxycodone 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 judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

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)
(Per 21 CFR 801.109)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K050733