K051088

JUN 24 2005

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

Device Name and Classification

(A) Classification Name:	Drug Mixture Calibrator Materials Class II, DKB (91 Toxicology), 21 CFR862.3200
Common/Usual Name:	Benzoylecgonine, Methamphetamine, Methadone, Morphine, Oxazepam, Secobarbital, Phencyclidine, Propoxyphene Calibrators
Proprietary Name:	None
(B) Classification Name:	Drug Mixture Control Materials; Class I, DIF (91 Toxicology), 21 CFR 862.3280
Common/Usual Name:	Benzoylecgonine, Methamphetamine, Methadone, Morphine, Oxazepam, Secobarbital, Phencyclidine, Propoxyphene Controls
Proprietary Name:	None

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.'s Multiple Analyte Urine Drugs of Abuse Calibrators and Controls are prepared according to the SAMHSA's guideline and confirmed with GC/MS.
Lin-Zhi International, Inc.' Multiple Analyte Urine Drugs of Abuse Calibrators and Controls are substantially equivalent to the Drugs of Abuse Urine Calibrators and Controls (Dade Behring, Microgenics), cleared under premarket notification K993755 (Dade Behring), K983159 (DRI, now Microgenics).

Device Description

All of the DAU Calibrators and Controls are liquid, and ready to use. These Calibrators and Controls do not have any especially unique technical characteristics. Each contains a known concentration of a specific drug analyte as a mixture.

The Negative DAU Calibrator is a processed, drug-free human urine matrix. The Low, Cutoff, Intermediate, and High Calibrators, as well as the 2 levels of Controls are prepared by spiking known concentrations of drug analyte into the Negative DAU Calibrator matrix. The various concentrations of each drug analyte in their corresponding calibrators and controls are summarized as follows:

Multiple Analyte Calibrators and Controls:

	Low Calibrator	Cutoff Calibrator	Intermediate Calibrator	High Calibrator		Control Level 1	Control Level 2
Material	ng/mL	ng/mL	ng/mL	ng/mL		ng/mL	ng/mL
Methamphetamine	250	500	750	1000		375	625
Secobarbital	100	200	500	1000		100	300
Oxazepam	100	200	500	1000		100	300
Benzoylecgonine	75	150	300	1000		110	190
Methadone	150	300	600	1000		225	375
Morphine	1000	2000	4000	6000		1500	2500
Phencyclidine	12.5	25	50	100		18	35
Propoxyphene	150	300	600	1000		225	375

Intended Use

The Multiple Analyte (Benzoylecgonine, Methamphetamine, Methadone, Morphine, Oxazepam, Secobarbital, Phencyclidine, and Propoxyphene) Urine Drugs of Abuse Calibrators intended for in vitro diagnostic use for the calibration of their respective enzyme immunoassays to detect *d*-methamphetamine, benzoylecgonine, opiate, benzodiazepines, barbiturates, methadone, phencyclidine or propoxyphene in human urine.

The Multiple Analyte (Benzoylecgonine, Methamphetamine, Methadone, Morphine, Oxazepam, Secobarbital, Phencyclidine, and Propoxyphene) Urine Drugs of Abuse Controls are intended for in vitro diagnostic use for the validation of their respective enzyme immunoassays to detect *d*-methamphetamine, benzoylecgonine, opiate, benzodiazepines, barbiturates, methadone, phencyclidine or propoxyphene in human urine.

Comparison to Predicate Device

LZI's Multiple Analyte urine DAU Calibrators and Controls are prepared according to the SAMHSA published guidelines. They are similar in intended use, matrix, and performance to the Microgenics's Drugs of Abuse Urine Calibrators and Controls, and Dade Behring Multi-anslyte Calibrators and Controls.
All spiked values of calibrators and controls were confirmed with GC/MS. Performance characteristics on precision, accuracy and stability are acceptable.

Conclusion

The information provided in the premarket notification demonstrates that the LZI's urine Multi-Analyte Drugs of Abuse Calibrators and Controls are safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 24 2005

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

Re: k051088
Trade/Device Name: Multiple Analyte Urine Calibrators and Controls
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: Class II
Product Code: DKB, DIF
Dated: April 26, 2005
Received: April 28, 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): K051088

Device Name: Multiple Analyte Urine Calibrators and Controls

Indications for Use:

The Multiple Analyte (Benzoylecgonine, Methamphetamine, Methadone, Morphine, Oxazepam, Secobarbital, Phencyclidine, and Propoxyphene) Urine Drugs of Abuse Calibrators are intended for in vitro diagnostic use for the calibration of their respective enzyme immunoassays to detect *d*-methamphetamine, benzoylecgonine, opiate, benzodiazepines, barbiturates, methadone, phencyclidine or propoxyphene in human urine.

The Multiple Analyte (Benzoylecgonine, Methamphetamine, Methadone, Morphine, Oxazepam, Secobarbital, Phencyclidine, and Propoxyphene) Urine Drugs of Abuse Controls are intended for in vitro diagnostic use for the validation of their respective enzyme immunoassays to detect *d*-methamphetamine, benzoylecgonine, opiate, benzodiazepines, barbiturates, methadone, phencyclidine or propoxyphene in human urine.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K051088

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)