APR 0 3 2002 K020769

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

Lin-Zhi International, Inc.
2391 Zanker Road, Suite 340
San Jose, CA 95131
Phone: (408) 944-0360
Fax: (408) 944-0359

Contact: Chiu Chin Chang, Ph.D.
VP, R&D

Device Name and Classification

(a) Classification Name:	Calibrators, Drug Specific; Class II, DLJ (91 Toxicology), 21 CFR 862.3200
Common/Usual Name:	Phencyclidine Calibrators, Opiate Calibrators, Cocaine Calibrators, and Amphetamine Calibrators
Proprietary Name:	None
(b) Classification Name:	Single (Specified) Analyte Controls (Assayed and Unassayed); Class I, LAS (91 Toxicology), 21 CFR 862.3280
Common/Usual Name:	Phencyclidine Controls, Opiate Controls, Cocaine Controls, and Amphetamines Controls
Proprietary Name:	None

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.' Single Analyte Urine Drugs of Abuse Calibrators and Controls are substantially equivalent to the Drugs of Abuse Urine Calibrators and Controls (Diagnostic Reagents, Inc., now Microgenics Corporation), cleared under premarket notification K983159.

Device Description

All of the Single Analyte Urine DAU Calibrators and Controls are human urine-based liquid, and ready to use. These Calibrators and Controls do not have any especially unique technical characteristics. When applicable, they contain known concentration of a specific drug analyte.

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:

	Phencyclidine EIA	**Opiate EIA**	**Cocaine Metabolite EIA**	**Amphetamines EIA**
Reference Material	Phencyclidine	Morphine	Benzoylecgonine	*d*-Methamphetamine
Low Calibrator	12.5 ng/mL	150 ng/mL	150 ng/mL	500 ng/mL
Cutoff Calibrator	25 ng/mL	300 ng/mL	300 ng/mL	1000 ng/mL
Intermediate Calibrator	50 ng/mL	600 ng/mL	1000 ng/mL	1500 ng/mL
High Calibrator	100 ng/mL	1000 ng/mL	3000 ng/mL	2000 ng/mL
Control Level 1	18 ng/mL	225 ng/mL	225 ng/mL	750 ng/mL
Control Level 2	32 ng/mL	375 ng/mL	375 ng/mL	1250 ng/mL

The nominal concentrations of the analyte in the calibrators and controls are determined and confirmed by GC/MS.

Intended Use

The Single Analyte Urine Drugs of Abuse (DAU) Calibrators are intended for in vitro diagnostic use for the calibration of their respective DAU enzyme immunoassays to detect phencyclidine, opiates, cocaine metabolite, or amphetamines in human urine.

The Single Analyte Urine Drugs of Abuse (DAU) Controls are intended for in vitro diagnostic use for the validation of their respective DAU enzyme immunoassays to detect phencyclidine, opiates, cocaine metabolite, or amphetamines in human urine.

Comparison to Predicate Device

LZI's Single Analyte Urine DAU Calibrators and Controls are similar in intended use, matrix, and performance to the DRI's Drugs of Abuse Urine Calibrators and Controls.

Similarities:

- Both are for the calibration and validation of DAU enzyme immunoassays to detect the same commonly abused drug analytes (phencyclidine, opiates, cocaine metabolite, or amphetamines) in human urine.

- The cutoff concentration for each analyte is the same per recommendations of The Substance Abuse and Mental Health Services Administration (SAMHSA).
- Both use 2 levels of Controls, and the concentrations are set at equal to or approximately ± 25% of the cutoff concentration for each analyte according to the SAMHSA guideline.
- The nominal concentrations of the analyte in the calibrators and controls are determined and confirmed by GC/MS.
- Both are urine-based liquids.
- Storage condition is the same, at 2°C to 8°C.
- Performance characteristics on precision, accuracy and stability are similar.

Differences:

Characteristics	DRI's DAU Urine Calibrators and Controls	LZI's Single Analyte Urine DAU Calibrators and Controls
No. of Analytes in each Calibrator or Control	All 4 drugs in each Calibrator or Control	Single drug only in each Calibrator or Control.
No. of Calibrators	3 levels* including the Negative Calibrator.	5 levels including the Negative Calibrator
Nomenclature/Labeling of Calibrators	Negative, Low (= Cutoff), and High	Negative, Low, Cutoff, Intermediate, and High
Concentration of Analyte(s)	Phencyclidine Controls: 20 and 35 ng/mL Cocaine High Calibrator: 1000 ng/mL	Phencyclidine Controls: 18 and 32 ng/mL, Cocaine High Calibrator: 3000 ng/mL

*Additional calibrators are now available. Currently 5 levels of calibrators (Cal 0, 1, 2, 3, and 4) are available from DRI/Microgenics Corp. (under "Multi-drug Urine Calibrators and Controls" product name).

Conclusion

The information provided in the premarket notification demonstrates that the LZI's Single Analyte Urine Drugs of Abuse Calibrators and Controls are substantially equivalent to previously approved predicate devices, notably the DRI's DAU Urine Calibrators and Controls, and 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

Chiu Chin Chang, Ph.D.
VP, R&D
Lin-Zhi International, Inc.
2391 Zanker Road – Suite 340
San Jose, CA 95131

APR 0 3 2002

Re: k020769
Trade/Device Name: Single Analyte Urine Drugs of Abuse Calibrators and Controls
Regulation Number: 21 CFR 862.3280; 21 CFR 862.3200
Regulation Name: Clinical toxicology control material; Clinical toxicology calibrator
Regulatory Class: Class I; Class II
Product Code: LAS; DLJ
Dated: February 28, 2002
Received: March 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): K020769

Device Name: **Single Analyte Urine Drugs of Abuse Calibrators and Controls**

Indications for Use:

The Single Analyte Urine Drugs of Abuse (DAU) Calibrators are intended for in vitro diagnostic use for the calibration of their respective DAU enzyme immunoassays to detect phencyclidine, opiates, cocaine metabolite, or amphetamines in human urine.

The Single Analyte Urine Drugs of Abuse (DAU) Controls are intended for in vitro diagnostic use for the validation of their respective DAU enzyme immunoassays to detect phencyclidine, opiates, cocaine metabolite, or amphetamines in human urine.

P. Bernhardt for J. Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020769

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

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

(Optional Format 1-2-96)