510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k051088

B. Purpose for Submission:
Notification of intent to manufacture and market the device: LZI Multiple Analyte Urine Drugs of Abuse Calibrators and Controls

C. Measurand:
Benzoylecgonine, Methamphetamine, Methadone, Morphine, Oxazepam, Secobarbital, Phencyclidine, and Propoxyphene

D. Type of Test:
Calibrators and Control Materials

E. Applicant:
Lin-Zhi International, Inc.

F. Proprietary and Established Names:
Proprietary Name – None
Established Name – Drug Mixture Calibrator
Drug Mixture Control

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.3200 Clinical toxicology, Drug Mixture
   21 CFR 862.3280 Clinical toxicology control material

2. Classification:
   Class II – calibrator
   Class I - control

3. Product code:
   DKB - calibrator
   DIF - control

4. Panel:
   Toxicology (91)

H. Intended Use:

1. Intended use:
   Refer to Indications for use

2. Indications for use: Multi-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.
Multi-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.

3. Special conditions for use statements: For in vitro diagnostic use
For prescription use

4. Special instrument requirements:
Automated clinical chemistry analyzer

I. Device Description: The calibrators and controls are liquid and ready to use. These calibrators and controls contain a known concentration of a mixture of specific drug analytes. The Negative Calibrator is a processed, drug free urine matrix. The Low, Cutoff, Intermediate and High Calibrators are prepared by spiking known concentrations of drug analyte into the Negative Calibrator matrix. Control Level 1 and 2 are prepared by spiking known concentrations of drug analyte into the Negative Calibrator matrix. The following concentrations of each drug analyte in their corresponding calibrators and controls are summarized:

	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

J. Substantial Equivalence Information:

1. Predicate device names: DRI, now Microgenics
   Dade Behring

2. Predicate 510(k) numbers: k993755
   k983159
3. Comparison with predicate:

Similarities			
Characteristic	**Lin-Zhi International**	**DRI, now Microgenics**	**Dade Behring, Syva**
Intended Use:	Intended for in vitro diagnostic use for the calibration and validation of LZI DAU enzyme immunoassays to detect methamphetamine, opiate, phencyclidine, benzoylecgonine, benzodiazepines, barbiturates, methadone, and propoxyphene in human urine.	Intended for in vitro diagnostic use for the calibration and validation of drug of abuse enzyme immunoassays for the detection of amphetamines, barbiturate, benzodiazepines, cocaine metabolite, methadone, methaqualone, morphine, phencyclidine and propoxyphene in human urine.	Used in the calibration of the Emit II Plus Barbiturate, Benzodiazepines, Cannabinoid, Cocaine Metabolite, Methadone, Methaqualone, Amphetamines, Methamphetamine, Opiate, Phencyclidine, and Propoxyphene Assays.
Levels	Total of 7 levels, including Negative.	Same	Total of 6 levels, including Negative.
Format	Liquid	Same	Same
Matrix	Urine	Same	Same
Storage	When not in use, bottles should be capped at all time and refrigerated at 2-8^{o} C.	The Calibrators and Controls should be stored refrigerated at 2-8^{o} C when not in use.	Always store the calibrators/controls refrigerated at 2-8^{o} C (36-46^{o}F) when not in use. Store upright. Do not freeze or expose to temperature above 32 ^{o} C (90^{o}F).

Differences			
Characteristic	**Lin-Zhi International**	**DRI, now Microgenics**	**Dade Behring, Syva**
Cutoffs for Benzoylecgonine, Methamphetamine	2004 SAMHSA guidelines: ng/mL 150, 500	Previous SAMHSA guidelines: ng/mL	Previous SAMHSA guidelines: ng/mL 300, 1000

		300, 1000	
Drugs	methamphetamine, opiate, phencyclidine, benzoylecgonine, benzodiazepines, barbiturates, methadone, and propoxyphene	amphetamines, barbiturate, benzodiazepines, cocaine metabolite, methadone, methaqualone, morphine, phencyclidine and propoxyphene	barbiturate, benzodiazepines, cannabinoid, cocaine metabolite, methadone, methaqualone, amphetamines, methamphetamine, opiate, phencyclidine, and propoxyphene

K. Standard/Guidance Document Referenced (if applicable): No Standard or Guidance Document was referenced in this submission

L. Test Principle: N/A

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

b. Linearity/assay reportable range: N/A

*c. **Traceability**, Stability, Expected values (controls, calibrators, or methods):*

The calibrators and controls are purchased from a supplier of analytical standards which provides documented traceability to drug standards. The supplier provides a certificate of analysis which includes the description of the material, reference material code and batch number, the certified values, the level of homogeneity and the data generated by GC/MS and HPLC. The concentrations of the calibrators and controls were confirmed with GC/MS. In addition some of the calibrators and controls are compared to calibration curves prepared from USP Reference Materials.

Stability

The calibrators and controls were split into two 15-mL vials with dropper tip and screw-on cap. When not in use, these vials were always capped. One set of aliquots containing the different levels of calibrators and controls were stored at 2-8^0 C while the other set of aliquots were stored at room temperature, 22-25^0 C. The signals produced by the assays were compared at day 1, day 143, day 189 and day 244. The data demonstrates that the analytes are stable in the matrix; there is no significant difference in rate produced by the two sets of calibrators/controls. Based on these studies, the stability is expected to be at least 18 months. The sponsor specifies the concentrations of materials evaluated in the studies, the frequency of testing, the method for testing the materials, and the environmental conditions of storage. Accelerated studies are being used by the sponsor to estimate the expiration date; however, on-going real time studies are being performed.

Expected Values
The Negative Calibrator is a processed, drug free urine matrix. The Low, Cutoff, Intermediate and High Calibrators are prepared by spiking known concentrations of drug analyte into the Negative Calibrator matrix. Control Level 1 and 2 are prepared by spiking known concentrations of drug analyte into the Negative Calibrator matrix. The concentrations are confirmed by GC/MS. Refer to section I for drug concentrations in the calibrators/controls.

d. Detection limit: N/A

e. Analytical specificity: N/A

f. Assay cut-off: N/A

2. Comparison studies:
   a. Method comparison with predicate device: N/A

   b. Matrix comparison: N/A

3. Clinical studies:
   a. Clinical Sensitivity: N/A

   b. Clinical specificity: N/A

   c. Other clinical supportive data (when a. and b. are not applicable): N/A

4. Clinical cut-off**:** N/A

5. Expected values/Reference range: N/A

N. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.