510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K201442

B Applicant

Diatron Group

C Proprietary and Established Names

Lin-Zhi International, Inc. (LZI) Methamphetamine Enzyme Immunoassay for Pictus Analyzers

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LAF	Class II	21 CFR 862.3610 - Methamphetamine Test System	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

Clearance of the LZI Methamphetamine assay (k113661) on the Diatron Pictus 700 clinical chemistry analyzer (k151487).

B Measurand:

d-Methamphetamine.

C Type of Test:

Qualitative, homogenous enzyme immunoassay.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Lin-Zhi International, Inc. (LZI) Methamphetamine Enzyme Immunoassay for Pictus Analyzers is intended for the qualitative determination of d-methamphetamine in human urine at a cutoff value of 500 ng/mL. The system was calibrated with d-methamphetamine. The assay provides a rapid screening procedure for determining the presence of d-methamphetamine in urine.

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

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Diatron Pictus 700 clinical chemistry analyzer

IV Device/System Characteristics:

A Device Description:

The LZI Methamphetamine Enzyme Immunoassay for Pictus Analyzers is a kit comprised of two reagents, an R1 and R2, which are bottled separately but sold together within the kit.
Antibody/Substrate Reagent (R1): Contains mouse monoclonal anti-methamphetamine antibodies, glucose-6-phosphate (G6P), nicotinamide adenine dinucleotide (NAD), stabilizers, and sodium azide (0.09%) as a preservative.
Enzyme-drug Conjugate Reagent (R2): Contains methamphetamine-labeled glucose- 6-phosphate dehydrogenase (G6PDH) in buffer with sodium azide (0.09 %) as a preservative.

B Principle of Operation:

The Lin-Zhi International, Inc. (LZI) Methamphetamine Enzyme Immunoassay for Pictus Analyzers 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, methamphetamine-labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. On the other hand, when drug is present in the sample, antibody binds to the free drug; and the unbound methamphetamine-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 a 340 nm primary wavelength.

V Substantial Equivalence Information:

A Predicate Device Name(s):
LZI Methamphetamine Enzyme Immunoassay

B Predicate 510(k) Number(s):
K113661

C Comparison with Predicate(s):

Device & Predicate Device(s):	K201442	K113661
Device Trade Name	Lin-Zhi International, Inc. (LZI) Methamphetamine Enzyme Immunoassay for Pictus Analyzers	LZI Methamphetamine Enzyme Immunoassay
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the qualitative determination of methamphetamine in human urine, at a cutoff value of 500 ng/mL.	Same
Mode of Detection	Photometric/photodiode	Same
Wavelength to measure Methamphetamine reagent reactions	340 nm	Same
Cut off level	500 ng/mL	Same
Sample type	Human urine	Same
General Device Characteristic Differences		
Results output	Qualitative	Qualitative and semi-quantitative
Instrument Platform	Diatron Pictus 700 analyzer	Cleared for clinical chemistry analyzers (open system)

VI Standards/Guidance Documents Referenced:

CLSI EP05-A2: User protocol for evaluation of Qualitative Test Performance; Approved Guideline, 2004.
CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline, 2003.
CLSI EP07-A2: Interference Testing in Clinical Chemistry, Approved Guideline, 2005.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Two studies were conducted to estimate the within-run and total imprecision of the test system following the CLSI EP05-A2 guidelines. Nine samples at 0, 125, 250, 375, 500, 625, 750, 875 and 1000 ng/mL of methamphetamine (cutoff, ±25 %, ±50 %, ±75%, and ±100 % of the cut-off) were evaluated in these studies. The within-run imprecision study was performed by testing each of the nine samples in 20 consecutive testing. The total imprecision study was performed by testing each of the nine samples in duplicate twice per day over 21 days. The data were assessed for "positive" and "negative" interpretation at either side of the 500 ng/mL cutoff. The results are shown in the two summary tables.

Total Precision

Level (ng/mL)	N	% Negative	# of Negative	% Positive	# of Positive
0	84	100%	84	0%	0
125	84	100%	84	0%	0
250	84	100%	84	0%	0
375	84	100%	84	0%	0
500	84	49%	41	51%	43
625	84	0%	0	100%	84
750	84	0%	0	100%	84
875	84	0%	0	100%	84
1000	84	0%	0	100%	84

Within Run Precision

Level (ng/mL)	N	% Negative	# of Negative	% Positive	# of Positive
0	20	100%	20	0%	0
125	20	100%	20	0%	0
250	20	100%	20	0%	0
375	20	100%	20	0%	0
500	20	60%	12	40%	8
625	19	0%	0	100%	19
750	20	0%	0	100%	20
875	20	0%	0	100%	20
1000	20	0%	0	100%	20

2. Linearity:

Not applicable as this is a qualitative assay.

3. Analytical Specificity/Interference:

Four structurally related compounds were tested in duplicate at the concentrations described in the table below. The reagents used in this assay are the same as those used in k113661, and the information describing analytical specificity of the device reviewed k113661 was also considered in this review.

Compound	Target Concentration (ng/mL)
d-Methamphetamine	500
d-Amphetamine	50,000
Methylenedioxyamphetamine (MDA)	72,500
Methylenedioxymethylamphetamine (MDMA)	1,500

Results:

Compound	Target Concentration (ng/mL)	P700 Qualitative Result	% Cross Reactivity
d-Methamhetamine	500	Positive	103.8
d-Amphetamine	50,000	Positive	1.1
Methylenedioxyamphetamine (MDA)	72,500	Positive	0.8
Methylenedioxymethylamphetamine (MDMA)	1,500	Positive	34.5

The sponsor claims that the results from the testing of these four compounds are similar to the results from the labeling of the predicate device. These results are adequate to demonstrate that the interference and cross reactivity testing performed in support of k113661 are representative of the expected cross reactivity and interference of these compounds with the candidate test system.

4. Assay Reportable Range:

Not applicable. This is a qualitative test.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The Lin-Zhi International, Inc. (LZI) Methamphetamine Enzyme Immunoassay for Pictus Analyzers is traceable to a commercially available d-methamphetamine standard.

6. Detection Limit:

Refer to the precision/reproducibility study section, above.

7. Assay Cut-Off:

Refer to the precision/reproducibility study section, above.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   A method comparison study was conducted using 98 human urine samples spanning in methamphetamine concentration from zero to 2000 ng/mL as measured by LC/MS method. One discordant result was obtained. The results are summarized in the below tables.

Candidate device results	Negative by LC/MS analysis	< 50 % of the cutoff concentration by LC/MS analysis	Near Cutoff Negative (Between 50 % below the cutoff and the cutoff concentration by LC/MS analysis)	Near Cutoff Positive (Between the cutoff and 50 % above the cutoff concentration by LC/MS analysis)	High Positive (Greater than 50 % above the cutoff concentration by LC/MS analysis)
Positive	0	0	1	20	28
Negative	15	23	11	0	0

Discordant Sample:

Sample #	LC/MS (ng/mL)	Candidate device result
61634620	488	Positive

2. Matrix Comparison:

   Not applicable. The test is only for urine specimens.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

D Clinical Cut-Off:

Not applicable; the device is for determining positive or negative. See Section above on Precision for analytical cutoff information.

E Expected Values/Reference Range:

Not applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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