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

A. 510(k) Number:
K032461

B. Analyte:
Ethyl Alcohol (Ethanol)

C. Type of Test:
Enzymatic Alcohol Dehydrogenase for the quantitative measurement of ethyl alcohol.

D. Applicant:
Lin-Zhi International, Inc.

E. Proprietary and Established Names:
Ethyl Alcohol Enzymatic Assay

F. Regulatory Information:

1. Regulation section:
   CFR 862.3040, Alcohol test system
2. Classification:
   Class II
3. Product Code(s):
   DIC, DKC, DNN
4. Panel:
   Toxicology 91

G. Intended Use:

1. Indication(s) for use:

   The Ethyl Alcohol Calibrators are intended for in vitro diagnostic use for the calibration of the Ethyl Alcohol Enzymatic Assay to determine the ethyl alcohol concentration in human urine, serum or plasma.

   The Ethyl Alcohol Controls are intended for in vitro diagnostic use for the validation of the Ethyl Alcohol Enzymatic Assay to determine ethyl alcohol in human urine, serum or plasma.

   The Ethyl Alcohol Enzymatic Assay is a homogeneous enzymatic assay with 0 and 100 mg/dL (0.1%) alcohol calibrators. The assay is intended for use in the quantitative analyses of ethyl alcohol in human urine, serum, or plasma. The assay is intended for professional use with a number of automated clinical chemistry analyzers.

   Measurements obtained by this device are used in the diagnosis and treatment of alcohol intoxication and poisoning.

2. Special condition for use statement(s):
   Prescription use only

3. Special instrument Requirements:
   Analyzers using this device must be able to maintain a constant temperature, pipette samples, mix reagents, measure enzyme rates at 340 nm, and time the reaction accurately.

H. Device Description:

The Ethyl Alcohol Assay calibrators have ethanol concentrations of 0 (negative) and 100 mg/dL in a phosphate buffer with sodium azide added as a preservative. The Ethyl Alcohol Assay controls have ethanol concentrations of 50 and 300 mg/dL in a phosphate buffer with sodium azide added as a preservative.

The Buffer Reagent (R1) contains tris-based buffer (50nM) with sodium azide. The Enzyme Reagent (R2) contains alcohol dehydrogenase (ADH), nicotinamide adenine dinucleotide (NAD, 10 nM), stabilizers, and sodium azide.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Ethyl Alcohol Assay
2. Predicate K number(s):
   K923783
3. Comparison with predicate:

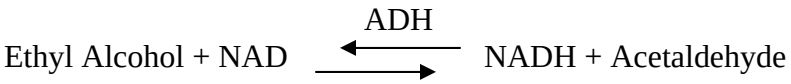
Similarities		
Item	**Device**	**Predicate**
Intended use	Plasma, serum, urine	Same
Method principal	Enzymatic (ADH)	Same
Reagent components	Alcohol dehydrogenase, Nicotinamide adenine dinucleotide	Same
Within-run precision (CV%)	@50 mg/dL:1.1 @100 mg/dL:0.8 @300 mg/dL:1.1	@50 mg/dL:2.7 @100 mg/dL:1.2 @300 mg/dL:0.6
Between-run precision (CV%)	@50 mg/dL:4.6	@50 mg/dL:9.0
	Differences	
Item	**Device**	**Predicate**
Sensitivity	3 mg/dL	10 mg/dL

J. Standard/Guidance Document Referenced (if applicable):

None referenced

K. Test Principle:

LZI's Ethyl Alcohol Enzymatic Assay is a homogeneous ready-to-use liquid reagents based on the alcohol dehydrogenase (ADH) enzymatic reaction. In the presence of nicotinamide adenine dinucleotide (NAD), ADH converts ethyl alcohol to acetaldehyde and reduces NAD to NADH. The ethyl alcohol concentration is then directly proportional to the ADH activity. The enzyme activity is measured at 340 nm wavelength.



L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within-run precision was calculated with data obtained using a Hitachi 717 (n=21 for all concentrations)

Conc (mg/dL)	50	100	200	300
Mean (mg/dL)	50.0	99.1	194.8	281.6
Std Dev	0.59	0.77	1.47	3.21
CV%	1.17	0.78	0.75	1.14

Between-run precision was calculated with data obtained using a Hitachi 717 (n=12; 12 runs over a 3 weeks period)

Conc (mg/dL)	50	100	200	300
Mean (mg/dL)	50.47	99.24	200.52	249.88
Std Dev	2.30	0.56	8.26	8.26
CV%	4.56	0.56	4.12	2.95

b. Linearity/assay reportable range:

3 to 600 mg/dL

c. Traceability (controls, calibrators, or method):

Controls and calibrators traceable to NIST ethanol standard

d. Detection limit:

3 mg/dL

e. Analytical specificity:

The following compounds were tested and the cross-reactivities measured:

Compound	Concentration	% cross-reactivity
Acetaldehyde	2000 mg/dL	0
Acetone	2000 mg/dL	0

n-Butanol	2000 mg/dL	1.5
Ethylene glycol	2000 mg/dL	0
Isopropanol	2000 mg/dL	0
Methanol	2000 mg/dL	0
n-Propanol	2000 mg/dL	11
Hemoglobin	800 mg/dL	0
Bilirubin	30 mg/dL	0
Triglycerides	1000 mg/dL	0

f. Assay cut-off:

N/A

2. Comparison studies:
   a. Method comparison with predicate device:
   A correlation study between the device (LZI) and the predicate, where n=55, yielded the following linear regression line:

   LZI = 0.991(predicate) + 11 mg/dL

   $R^2 = 0.995$

   b. Matrix comparison:
   Both the device and the predicate measure ethyl alcohol in plasma, serum, or urine.
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:
   Ethyl alcohol is not present in detectable concentrations in healthy adults who have not consumed ethanol

M. Conclusion:

Based upon the information provided for the file, I recommend that the LZI Ethyl Alcohol Enzymatic Assay is substantially equivalent to the predicate device.