July 31, 2020

Diatron Group
% Erika Ammirati
President
Ammirati Regulatory Consulting
575 Shirlynn Court
Los Altos, CA 94022

Re: K201442
Trade/Device Name: Lin-Zhi International, Inc. (LZI) Methamphetamine Enzyme Immunoassay for Pictus Analyzers
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine Test System
Regulatory Class: Class II
Product Code: LAF
Dated: May 29, 2020
Received: June 1, 2020

Dear Erika Ammirati:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201442

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

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

July 31, 2020

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K201442.

807.92 (a)(1): Name: Diatron, US, Inc.
Address: 12601 N.W. 115 Avenue, Suite A113
Medley, FL 34178

Phone: 833-228-7931
FAX: 786-264-9460
Contact: Mr. Frank Matusazak

807.92 (a)(2): Device name- trade name and common name, and classification

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

Common Name: Homogeneous Enzyme Immunoassay for Drug of Abuse Methamphetamine Enzyme Immunoassay.

Classification Name(s):
21 CFR § 862.3610 - Methamphetamine test system
Product Code: LAF
Class II
Panel: Toxicology 91

807.92 (a)(3): Identification of the legally marketed predicate devices

LZI Methamphetamine Immunoassay reagent cleared under K113661

807.92 (a)(4): Device Description

Methamphetamine
Lin-Zhi International, Inc. (LZI) Methamphetamine Enzyme Immunoassay for Pictus Analyzers is intended for the qualitative determination of methamphetamine in human urine, at a cutoff value of 500 ng/mL.

The assay is designed for laboratory use by trained professionals with various automated clinical chemistry analyzers.

This assay provides a rapid screening procedure for assessing the presence of d-methamphetamine in urine. The assay provides only a preliminary analytical result reported as a positive or negative. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive. The analyzer photometer reads the absorbance at 340nm at

time intervals dictated by the Methamphetamine application stored in the analyzer memory, and the change in absorbance is calculated automatically.

807.92 (a)(5): Intended 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.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

The following chart describes similarities and differences between the two test systems.

Characteristic	**Candidate System Lin-Zhi International, Inc. (LZI) Methamphetamine Enzyme Immunoassay for Pictus Analyzers**	**Predicate System** LZI Methamphetamine Immunoassay **(K113661)**
Instrument Platform	Pictus Analyzers	"Cleared for chemistry analyzers" (open system)
Mode of Detection/Photometric Detector	Photometric/Photodiode	Same
Wavelength to measure Methamphetamine reagent reactions	340nm	Same

Characteristic	Candidate System Lin-Zhi International, Inc. (LZI) Methamphetamine Enzyme Immunoassay for Pictus Analyzers	Predicate System LZI Methamphetamine Immunoassay **(K113661)**
Intended Use & Sample type	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.	The LZI Methamphetamine Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of d-methamphetamine in human urine, at the cutoff value of 500 ng/mL. The assay is designed for professional use with a number of automated chemistry analyzers. The semi-quantitative mode is for purposes of (1) enabling laboratories to determine an appropriate dilution of specimen for confirmation by a confirmatory method such as GCMS or LCMS or (2) permitting laboratories to establish quality control procedures. The LZI Methamphetamine Drugs of Abuse (DAU) Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Methamphetamine Enzyme Immunoassay at a cutoff value of 500 ng/mL. The LZI Methamphetamine Drugs of Abuse (DAU) Controls are for use as assayed quality control materials to monitor the precision of the LZI Methamphetamine Enzyme Immunoassay at a cutoff value of 500 ng/mL. The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

Characteristic	Candidate System Diatron Pictus 700 Analyzer with LZI Methamphetamine EIA	Predicate System Hitachi 717 Analyzer with LZI Methamphetamine EIA (K113661)
Cut-off: Negative/Positive level	500 ng/mL	Same
Device Class, Regulation Code	Class II, 21 CFR § 862.3610 - Methamphetamine reagent, LAF	Same

807.92 (b)(1): Brief Description of Nonclinical Data

Precision:

Studies for within-run and total precision were performed at nine MAMP levels following CLSI EP05-A2. From these results, means, standard deviations, and percent coefficients of variation were calculated, and summarized data are shown below. In addition to the absorbance outputs, the data were assessed for "positive" and "negative" interpretation at either side of the 500 ng/mL cutpoint.

Total Precision

Level	Samples	% Negative	# Neg	% Positive	# Pos
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	Samples	% Negative	# Neg	% Positive	# Pos
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

Cross Reactivity

Four structurally related compounds were tested in duplicate at the concentrations described below. Other structurally and non-structurally related compounds were not tested as this system

utilizes reagents that have already been assayed and described.

Compound	Target Concentration (ng/mL)
d-Mathamhetamine M-020	500
d-Amphetamine A-008	50,000
Methylenedioxyamphetamine (MDA) M-012	72,500
Methylenedioxymethylamphetamine (MDMA) M-013	1,500

The results are shown below, followed by the results as generated on the Hitachi 717 (predicate system).

Pictus P700

Compound	Target Concentration (ng/mL)	P700 Qualitative Result
d-Methamhetamine M-020	500	Positive
d-Amphetamine A-008	50,000	Positive
Methylenedioxyamphetamine (MDA) M-012	72,500	Positive
Methylenedioxymethylamphetamine (MDMA) M-013	1,500	Positive

Reference

Compound	Target Concentration (ng/mL)	Hitachi 717 Qualitative Result
d-Mathamhetamine M-020	500	211
d-Amphetamine A-008	50,000	212.1
Methylenedioxyamphetamine (MDA) M-012	72,500	210.1
Methylenedioxymethylamphetamine (MDMA) M-013	1,500	207.8

The results demonstrate that cross-reactivity of the reagents with the Pictus 700 was the same as that demonstrated with the same reagents on the Hitachi 717.

Accuracy - Method Comparisons:

Ninety-eight (98) human urine samples with a span MAMP values between zero and 2,000 ng/mL (as value assigned by LC/MS) were assayed with the Pictus 700 system. As the Pictus 700 system reports qualitative results with a cutoff at 500 ng/mL, study success was defined as follows:

1) LC/MS results reported as 350 ng/mL or lower must be negative.
2) LC/MS results reported as 650 ng/mL or higher must be reported as positive.
3) LC/MS results reported between 351 and 649 ng/mL must be at least 95% congruent in terms of negative and positive results on either side of the 500 ng/mL cutoff.
4) Pictus 700 results should determine negative and positive results in a similar fashion

to the LZI MAMP reagent submission data used to obtain clearance (K113661). Results are shown below.

Cut-Off Value 500 ng/mL **Pictus 700 Methamphetamine Tests vs LC/MS Reference**

	Zero Negative	LC/MS <50% of COV Negative ng/mL (<251 ng/mL)	LC/MS <70% of COV Negative (251-350 ng/mL)	LC/MS Near CO Negative (351-499 ng/mL)	LC/MS Near CO Positive (501-650ng/mL)	LC/MS >30% of CO Positive (651-750ng/mL)	LC/MS >50% of COV Positive (751-1000ng/mL)	LC/MS Very High Positive (>1000 ng/mL)	% Agree
Positive (48 samples)	0	0	0	1	15	5	7	21	100.0%
Negative (50 samples)	15	23	7	4	0	0	0	0	98.0%

Discordant Sample 61634620 Candidate Positive (514) LC/MS 488

Cut-Off Value (COV) 500 ng/mL **Hitachi 717 Methamphetamine Tests vs LC/MS Reference**

	Zero Negative	1 to 250 ng < 50% of the COV Negative	250 ng to 500 ng < COV Negative	500 ng to 750 ng > COV positive	High Positive >750ng	% Agreement
Positive (47 samples	0	0	0	9	37	97.9%
Negative (48 samples	20	16	12	1	0	100.0%

Discordant result LC/MS Result 654 ng/mL
Test result Hitachi 717 Negative

On-board Methamphetamine Reagent Stability

The MAMP reagent has been previously cleared, and there have been no material changes to the components or manufacturing process since its clearance. An on-board reagent stability study was undertaken to validate open vial stability for the LZI MAMP reagent on the Pictus 700 for a two-week period.

Sufficient quantity of LZI MAMP reagent was added to a Pictus 700 reagent cartridge and loaded onto the Pictus 700 analyzer's cooled reagent tray. Three fresh sample pools with known methamphetamine concentrations were analyzed on Day 1, 3, 6, 7, 10, 13, 14 and 17 in duplicate or triplicate, and mean results for each day are compared to the Day 1 levels.

The LZI Methamphetamine reagent is stable on-board the Pictus 700 analyzer for at least 14 days, and calibration frequency is defined at 7 days.

807.92 (b)(2): Brief Description of Clinical Data
Not applicable

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing
The Diatron Pictus 700 Chemistry Analyzer using LZI-MAMP reagent for the qualitative determination of MAMP in human urine is substantially equivalent to the LZI- MAMP reagent when used on the Hitachi 717, cleared under K113661. The system is an effective screening system for validated drugs of abuse screening.