December 3, 2018

Lin-Zhi International, Inc.
Bernice Lin, VP Operations
2945 Oakmead Village Court
Santa Clara, CA 95051

Re: k181159
Trade/Device Name: LZI Fentanyl Enzyme Immunoassay
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG
Dated: October 25, 2018
Received: October 25, 2018

Dear Bernice Lin:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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)*
k181159

Device Name
LZI Fentanyl Enzyme Immunoassay

Indications for Use *(Describe)*
The LZI Fentanyl Enzyme Immunoassay is intended for the qualitative determination of norfentanyl in human urine at the cutoff value of 5 ng/mL when calibrated against norfentanyl. The assay is designed for prescription use with a number of automated clinical chemistry analyzers.

The assay provides only a preliminary analytical result. A more specific alternative chemical method (e.g., gas or liquid chromatography and mass spectrometry) must be used in order to obtain a confirmed analytical result.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

k181159

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.

Submitted On

April 26, 2018

Last Updated On

November 27, 2018

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:

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Santa Clara, CA 95051
Phone: (408) 970-8811
Fax: (408) 970-9030
e-mail: bclin@lin-zhi.com

Contact: Bernice Lin, Ph.D.
VP Operations

Device Name and Classification

Classification Name:	Enzyme Immunoassay, Opiates Class II, DJG (91 Toxicology), 21 CFR 862.3650
Common Name:	Homogeneous Fentanyl Enzyme Immunoassay
Proprietary Name:	LZI Fentanyl Enzyme Immunoassay

Legally Marketed Predicate Device(s)

The LZI Fentanyl Enzyme Immunoassay is substantially equivalent to the Immunalysis SEFRIA Fentanyl Urine Enzyme Immunoassay (k161216) manufactured by Immunalysis Corporation. The LZI Fentanyl Enzyme Immunoassay is identical or similar to its predicate in terms of intended use, method principle, device components, and clinical performance.

Device Description

The LZI Fentanyl Enzyme Immunoassay is a homogeneous enzyme immunoassay with ready-to-use liquid reagents. 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, norfentanyl-labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. On the other hand, when free drug is present in the sample, antibody would bind to free drug; the unbound norfentanyl-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 340 nm.

The LZI Fentanyl Enzyme Immunoassay is a kit comprised of two reagents, an R_1 and R_2, which are bottled separately but sold together within the kit.

The R_1 solution contains mouse monoclonal anti-fentanyl antibody, glucose-6-phosphate (G6P) nicotinamide adenine dinucleotide (NAD), stabilizers, and sodium azide (0.09 %) as a preservative. The R_2 solution contains glucose-6-phosphate dehydrogenase (G6PDH) labeled with fentanyl in buffer with sodium azide (0.09 %) as a preservative.

The LZI Fentanyl Enzyme Immunoassay calibrators and controls are designated for use at the 5 ng/mL cutoff contain 0, 2.5, 3.75, 5, 6.25, 10, and 20 ng/mL of norfentanyl in human urine with sodium azide (0.09 %) as a preservative. These five calibrators and two controls are sold as individual bottles.

Intended Use

The LZI Fentanyl Enzyme Immunoassay is intended for the qualitative determination of norfentanyl in human urine at the cutoff value of 5 ng/mL when calibrated against norfentanyl. The assay is designed for prescription use with a number of automated clinical chemistry analyzers.

The assay provides only a preliminary analytical result. A more specific alternative chemical method (e.g., gas or liquid chromatograpy and mass spectrometry) must be used in order to obtain a confirmed analytical result. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

Comparison to Predicate Device

The LZI Fentanyl Enzyme Immunoassay is substantially equivalent to the Immunalysis SEFRIA Fentanyl Urine Enzyme Immunoassay which was cleared by the FDA under the premarket notification k161216 for its stated intended use.

The following table compares the LZI Fentanyl Enzyme Immunoassay with the predicate device.

Device Characteristics	**Subject Device** LZI Fentanyl Enzyme Immunoassay, Norfentanyl Calibrators and Controls	**Predicate Device (k161216)** Immunalysis SEFRIA Fentanyl Urine Enzyme Immunoassay and Fentanyl Calibrators
Intended Use	The LZI Fentanyl Enzyme Immunoassay, when used in conjunction with the AU680 automated clinical system analyzer, is intended for the qualitative determination of norfentanyl in human urine at the cutoff value of 5 ng/mL when calibrated against norfentanyl. The assay is designed for prescription use with a number of automated clinical chemistry analyzers. ***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.***	For the qualitative determination of the presence of Fentanyl in human urine at a cutoff of 1 ng/mL
Detection	Absorbance change measured spectrophotometrically at 340 nm	Absorbance change measured spectrophotometrically at 570 nm
Analyte	Norfentanyl	Fentanyl
Cutoff	5 ng/mL	1 ng/mL
Matrix	Urine	Urine
Calibrator Levels	5 ng/mL	One negative and three levels (0, 1, 2 and 4 ng/mL
Control Levels	3.75 and 6.25 ng/mL	N/A
Storage	2-8 ºC until expiration date	2-8 ºC until expiration date

Performance Characteristics Summary:

AU680 Analyzer

Precision: 5 ng/mL Cutoff

Precision: Qualitative, results in ΔOD, mAU

Norfentanyl Concentration	Within Run (N=22)			Total Precision (N=88)		
	Mean	SD	% CV	Mean	SD	% CV
0 ng/mL	0.1	0.1	N/A	0.1	0.3	N/A
1.25 ng/mL	17.2	2.9	16.5%	17.2	3.6	20.8%
2.5 ng/mL	38.4	2.7	7.2%	38.4	3.2	8.4%
3.75 ng/mL	62.5	2.3	3.8%	62.5	3.6	5.7%
5 ng/mL	84.4	2.7	3.1%	84.4	3.3	4.0%
6.25 ng/mL	107.3	2.8	2.6%	107.3	3.6	3.4%
7.5 ng/mL	128.9	3.0	2.3%	128.9	4.1	3.2%
8.75 ng/mL	151.5	3.0	2.0%	151.5	4.1	2.7%
10 ng/mL	169.2	3.8	2.3%	169.2	4.3	2.6%

Qualitative Positive/Negative Results:

5 ng/mL Cutoff Result:		Within Run (N=22)		Total Precision (N=88)	
Norfentanyl Concentration	% of Cutoff	Number of Determination	EIA Result	Number of Determination	EIA Result
0 ng/mL	0 %	22	22 Negative	88	88 Negative
1.25 ng/mL	25.0 %	22	22 Negative	88	88 Negative
2.5 ng/mL	50.0 %	22	22 Negative	88	88 Negative
3.75 ng/mL	75.0 %	22	22 Negative	88	88 Negative
5 ng/mL	100.0 %	22	2 Pos/ 20 Neg	88	26 Pos/ 62 Neg
6.25 ng/mL	125.0 %	22	22 Positive	88	88 Positive
7.5 ng/mL	150.0 %	22	22 Positive	88	88 Positive
8.75 ng/mL	175.0 %	22	22 Positive	88	88 Positive
10 ng/mL	200.0 %	22	22 Positive	88	88 Positive

Method Comparison - Clinical Samples:

From a total of one-hundred and one (101) clinical unaltered samples,
Qualitative Data: 100.0 % agreement with positive, 86.5 % agreement with negative samples

Endogenous Compound Interference, Specificity, and Cross-Reactivity:

Interference was observed with Boric Acid at 1% w/v and with dextromethorphan. No other significant undesired cross-reactants or endogenous substance interference was observed.

Performance Characteristics Summary: (continued)
AU680 Analyzer

Summary:
The information provided in this pre-market notification demonstrates that the LZI Fentanyl Enzyme Immunoassay is substantially equivalent to the legally marketed predicate device for its general intended use. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available predicate device as confirmed by chromatography/mass spectrometry (GC/MS or LC/MS), an independent analytical method. The information supplied in this pre-market notification provides reasonable assurance that the LZI Fentanyl Enzyme Immunoassay is safe and effective for its stated intended use.