April 19, 2018

Infrared Laboratory Systems, LLC (dba Synermed)
Julie Paschal
Regulatory Affairs Specialist
17408 Tiller Court, Suite 1900
Westfield, IN 40674

Re: k172416
Trade/Device Name: Synermed Opiate Enzyme Immunoassay
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG
Dated: February 28, 2018
Received: March 5, 2018

Dear Julie Paschal:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*
k172416

Device Name
Synermed Opiate Enzyme Immunoassay

Indications for Use *(Describe)*
The Synermed Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of opiates in human urine at a cutoff value of 300 ng/mL when calibrated against morphine. The assay is designed for professional use with a number of automated clinical chemistry analyzers. This assay is for prescription use only. The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmatory method such as GCMS or permitting laboratories to establish quality control procedures.

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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k172416

510(k) Summary

1. **Company Information**

Infrared Laboratory Systems, LLC
17408 Tiller Court Suite 1900
Westfield, Indiana 46074
Telephone; (317) 896-1565
FAX: (317) 896-1566

2. **Contact Information**

Julie Paschal
Regulatory Affairs Specialist
Telephone: 336-269-5069
Email: jpaschal@slplabs.com

3. **Date Prepared**: August 3rd 2017

4. **Device Trade Name**: Synermed Opiate Enzyme Immunoassay

5. **Common Name**: Opiate Enzyme Immunoassay

6. **Classification Name**: Enzyme Immunoassay, Opiate

7. **Classification Regulation**: 21CFR862.3650

8. **Classification Product Code**: DJG

9. **Panel**: Toxicology (91)

10. **Reagent Device Classification**:

Pro Code	Classification Regulation	Classification Name	Device Class	Panel
DJG	862.3650	Enzyme Immunoassay, Opiate	Class II	91

11. Identification of Predicates:

K-number	Manufacturer	Product	Method
K110298	Lin-Zhi International	Enzyme Immunoassay, Opiate	Enzyme Immunoassay

12. Device Description

Synermed Opiate Enzyme Immunoassay
The Synermed Opiate Enzyme Immunoassay is ready to use. The composition of the Synermed Opiate Enzyme Immunoassay Reagent is as follows:
Antibody/Substrate Reagent (R1): Contains mouse monoclonal anti-morphine antibody, opiate-6-phosphate (G6P), nicotinamide adenine dinucleotide (NAD), stabilizers, and sodium azide (0.09 %) as a preservative.
Enzyme-drug Conjugate Reagent (R2): Contains morphine-labeled opiate-6-phosphate dehydrogenase (G6PDH) in buffer with sodium azide (0.09 %) as a preservative.

Intended Use

Synermed Opiate Enzyme Immunoassay
The Synermed Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of opiates in human urine at a cutoff value of 300 ng/mL when calibrated against morphine. The assay is designed for professional use with a number of automated clinical chemistry analyzers. This assay is for prescription use only. The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmatory method such as GCMS or permitting laboratories to establish quality control procedures.

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.

13. Comparison of Technological Characteristics with the Predicate Device

The new device is substantially equivalent to the predicate because it has the same intended use and has the same or similar technological characteristics including safety and effectiveness. The same specimen type can be analyzed to detect the amount of absorbance which is proportional to the concentration of the analyte in the specimen.

Items	**Candidate Device: Synermed IR-500 Opiate Enzyme Immunoassay**	**Predicate Device: Lin-Zhi Opiate Immunoassay**

Similarity/Difference		
Intended Use	The Synermed Opiate Enzyme Immunoassay The Opiate Enzyme Immunoassay from Immunoassay, when used in conjunction with Synermed IR series analyzers is intended for qualitative and semi-quantitative determination of morphine in human urine at a cutoff value of 300 ng/mL in urine. The assay is designed for professional use.	Same
Analyte	Morphine	Same
Specimen	Urine	Same
Cutoff	300 ng/mL	Same
Matrix	Urine	Same
Storage	2-8°C until expiration date	Same
Calibration/QC	Programmable Cal/QC	Same

15. Summary of Performance Testing

The purpose of the performance studies was to validate that the previously cleared reagents have the same performance characteristics on the proposed new analyzer (Synermed IR-500) as compared to the previously cleared Hitachi 717. The sponsor has chosen the representative analyte Opiate using urine as the representative sample matrix.

Analytical Performance

a. Precision/Reproducibility

Verification of semi-quantitative precision on the Synermed IR-500 was accomplished by implementing the study protocol laid out in NCCLS document **EP05-A3**, **Chapter 3.** Qualitative verification was accomplished by implementing the study protocol laid out in **CLSI EP12-A, Chapter 7.** Eleven concentrations of pooled human urine were run for opiate. Each aliquot was run in duplicate twice a day for twenty days for a total of 80 measurements at each concentration. The mean, standard deviation and coefficient of variation were determined for opiate at each concentration. For qualitative analysis, the results were compared to the expected result (negative expected results should yield negative results in the precision study). Each level of pooled human urine was confirmed by Ultra High-Performance Liquid Chromatography Tandem Mass Spectrometry, for verification chromatography refer to Appendix A: UHPLC-MSMS Raw Data.

Table 3 – Semi-Quantitative Opiate Precision Comparison to Lin-Zhi Results (per Package Insert)

Opiate Tested Concentrations	IR-500 Within-Run Expected	Results Pos/Neg	IR-500 Run-To-Run Expected	Results Pos/Neg
0 ng/mL	-	-	-	-
75 ng/mL	-	-	-	-
150 ng/mL	-	-	-	-
225 ng/mL	-	-	-	-
300 ng/mL	+	+	+	+
375 ng/mL	+	+	+	+
450 ng/mL	+	+	+	+
525 ng/mL	+	+	+	+
600 ng/mL	+	+	+	+
800 ng/mL	+	+	+	+
1000 ng/mL	+	+	+	+

Table 4 – Qualitative Opiate Precision Comparison to Lin-Zhi Results (per Package Insert)

Opiate Tested Concentrations	Within-Run Results Pos/Neg	Run-to-Run Results Pos/Neg	Expected Result (Pos/Neg)
0 ng/mL	-	-	-
75 ng/mL	-	-	-
150 ng/mL	-	-	-
225 ng/mL	-	-	-
300 ng/mL	+	+	+
375 ng/mL	+	+	+
450 ng/mL	+	+	+
525 ng/mL	+	+	+
600 ng/mL	+	+	+
800 ng/mL	+	+	+
1000 ng/mL	+	+	+

b. Linearity/Reportable Range

Linearity studies were designed using **NCCLS EP06-A**. Samples were prepared by intermixing a high urine pool with a low urine pool to obtain ten concentrations across the measuring range with four replicates at each concentration. The observed values were compared to the expected values and are summarized below. Each level of pooled human urine was confirmed by Ultra High-Performance Liquid Chromatography Tandem Mass Spectrometry.

Table 3 – Opiate Analytical Recovery

"Expected" Value (ng/mL)	Mean Observed Value (ng/mL)	Recovery (%)
1250	1032.5	82.6
1100	907.3	82.5
1000	875.0	87.5
800	662.0	82.8
600	513.8	85.6
450	369.5	82.1
300	240.5	80.2
225	192.3	85.4
150	135.0	90.0
75	67.3	89.7
25	15.5	62.0
0	11.0	#DIV/0!

c. Analytical Specificity

The following endogenous compounds were spiked into urine spiked with morphine to +/- 25% of cutoff (225 and 375 ng/mL). The spiked solutions were evaluated on the IR-500. The substances listed in the following table were determined not to interfere at the concentrations tested.

Compound	Concentration ng/mL	-25% Cutoff		+25% Cutoff	
		Qual	Semi-Quant	Qual	Semi-Quant
Acetone	1000	Negative	Negative	Positive	Positive
Ascorbic Acid	1500	Negative	Negative	Positive	Positive
Creatinine	500	Negative	Negative	Positive	Positive
Ethanol	1000	Negative	Negative	Positive	Positive
Glucose	3000	Negative	Negative	Positive	Positive
Hemoglobin	300	Negative	Negative	Positive	Positive
Human Serum Albumin	500	Negative	Negative	Positive	Positive
Riboflavin	0.3	Negative	Negative	Positive	Positive
Sodium Chloride	6000	Negative	Negative	Positive	Positive
Urea	6000	Negative	Negative	Positive	Positive

d. Comparison Studies

Method comparison was performed according to **CLSI EP09-A3**, 100 samples for opiate were tested on the IR-500, Hitachi 717 chemistry analyzers, and Ultra High-Performance Liquid Chromatography Tandem Mass Spectrometry (LC-MSMS). The study results are summarized in the table below. Each level of pooled human urine was confirmed by Ultra High-Pressure Liquid Chromatography Tandem Mass Spectrometry, for verification chromatography refer to Appendix A: UHPLC-MSMS Raw Data.

Table 2 - IR-500 Summary of Semi-Quantitative Comparison Data vs LCMS

Candidate Device Results	Negative	Low Negative (< 50% of the cutoff by LC/MS)	Near Cutoff Negative (50% below the cutoff to the cutoff by LC/MS)	Near Cutoff Positive (50% above the cutoff to the cutoff by LC/MS)	Percent Agreement with LC/MS
Positive	0	0	0	11	91%
Negative	5	19	30	4	100%

Discrepant Sample #	Drug/Metabolite LC/MS value based on cross reactivity profile	POS/NEG Result	POS/NEG Result
50	321.82 ng/mL (Morphine)	Positive	Negative
53	306.20 ng/mL (Morphine)	Positive	Negative
57	314.80 ng/mL (Morphine)	Positive	Negative
58	327.67 ng/mL (Morphine)	Positive	Negative

16. Conclusions

The new device is substantially equivalent to the predicate because it has the same intended use and has the same or similar technological characteristics that do not raise new types of questions of safety and effectiveness.