DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

INFRARED LABORATORY SYSTEMS, LLC (DBA SYNERMED)
JULIE PASCHAL
REGULATORY AFFAIRS SPECIALIST
17408 TILLER COURT SUITE 1900
WESTFIELD IN 40674

June 24, 2016

Re: K153692
Trade/Device Name: Synermed Glucose Reagent, Synermed IR-1200 Chemistry Analyzer
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CGA, JJE
Dated: June 20, 2016
Received: June 21, 2016

Dear Ms. 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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153692

Device Name
Synermed Glucose Reagent
Synermed IR-1200 Chemistry Analyzer

Indications for Use *(Describe)*
The Synermed Glucose Reagent is for the in vitro quantitative measurement of glucose in serum on the Synermed IR-1200 Chemistry Analyzer. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia and of pancreatic islet cell carcinoma.

The Synermed IR-1200 Chemistry Analyzer is intended for in vitro diagnostic use as a multiparameter chemistry instrument that quantitates the levels of constituents in serum. The analyzer is an automated, random access, computer controlled, clinical chemistry analyzer for clinical chemistry tests. The instrument provides in vitro quantitative measurements for glucose in serum. The device is intended for use only in clinical laboratories.

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

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: 336-235-3057
   Email: jpaschal@slplabs.com

3. **Date Prepared**: June 20, 2016

4. **Device Trade Name**: Synermed Glucose Reagent; Synermed IR-1200 Chemistry Analyzer

5. **Common Name**: Glucose test system; Chemistry Analyzer

6. **Classification Name**: Glucose test, Class II; Discrete photometric chemistry analyzer for clinical use, Class I

7. **Classification Regulation**: 21CFR862.1345, 21CFR862.2160

8. **Classification Product Code**: CGA, JJE

9. **Panel**: Chemistry (75)

10. **Reagent Device Classification**:

Pro Code	Classification Regulation	Classification Name	Device Class	Panel
CGA	862.1345	Glucose test system	Class II	75
JJE	862.2160	Discrete photometric chemistry analyzer for clinical use	Class I	75

11. Identification of Predicates:

K-number	Manufacturer	Product
K872494	Boehringer Mannheim Corp (Roche)	Hitachi 717 chemistry analyzer
K903063	Synermed	Synermed Glucose Reagent

12. Device Description

Synermed IR-1200 Glucose Reagent
The Synermed Glucose is ready to use. The composition of the Synermed Glucose Oxidase Reagent is as follows: 280 µmol/L N-sulfopropyl-N-ethyl-3, 5-dimethylaniline, 280 µmol/L ampyrone, 1400 U/L peroxidase (horseradish) and 18,000 U/L glucose oxidase.

Synermed IR-1200 Chemistry Analyzer
The IR-1200 Chemistry Analyzer is a multiparameter chemistry instrument that quantitates the levels of analytes in serum using spectrophotometric measurement. The system uses Synermed liquid-stable reagent systems that have been previously cleared by FDA.

The IR-1200 Chemistry Analyzer is a discrete analyzer with STAT priority capabilities and an externalized computer. The instrument features a user-friendly software operating system, optical unit, precision pipetting and electronic system. Twelve wavelengths are included ranging from 340 nm to 800 nm. The instrument's capabilities include: sample pipetting, reagent pipetting, anti-interference, mixing, pre-heating, reaction monitoring, calculation, display and printing of results. After the measurement is complete, the system rinses and dries the cuvettes. The system automates the manual functions and, as a result, it enhances efficiency, diminishes errors, thus improving the accuracy and precision of test results.

13. Intended Use

Synermed Glucose Reagent
The Synermed Glucose Reagent is for the in vitro quantitative measurement of glucose on serum on the Synermed IR-1200. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and of pancreatic islet cell carcinoma.

Synermed IR-1200 Chemistry Analyzer
The Synermed IR-1200 analyzer is intended for in vitro diagnostic use as a multiparameter chemistry instrument that quantitates the levels of constituents in serum. The analyzer is an automated, random access, computer controlled, clinical chemistry analyzer for clinical chemistry tests. The instrument provides in vitro quantitative measurements for glucose in serum. The device is intended for use only in clinical laboratories.

14. 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 and both analyzers use spectrophotometry to detect the amount of absorbance which is proportional to the concentration of the analyte in the specimen. Both analyzers wash and reuse PMMA cuvettes as well as use the same temperature ranges and the incubation for the reaction occurs at 37°C. Analyzer performance was quantified using the same previously cleared reagent systems.

Items	**Candidate Device: Synermed IR-1200 Chemistry Analyzer**	**Predicate Device: Roche/Boehringer Mannheim Hitachi 717 Chemistry Analyzer**
Similarity/Difference		
Intended Use	The Synermed IR-1200 chemistry analyzer is an automated clinical analyzer for in vitro diagnostic use only in clinical laboratories. It is intended to be used for a variety of assay methods. The analyzer provides in vitro quantitative determinations for glucosee in serum samples.	Same
Environment	Clinical laboratory use only	Same
Specimen	Serum	Same
Power	220 VAC, 50/60 Hz	115 VAC, 60 Hz
Analytical Methods	Endpoint, kinetic	Same
Calibration Methods	Linear and Nonlinear calibration	Same
Throughput (Max)	800 photometric tests/ hour	600 photometric tests/ hour
Calibration/QC	Programmable Cal/QC, will repeat automatically if out of range	Same
Photometer wavelength	340-800 (12 wavelengths)	Same
Linear Absorbance Range	0-3.3 Absorbance	0-3.2 Absorbance
Reaction Cuvettes	Reusable PMMA (Polymethylmethacrylate)	Same
Lightpath	0.5cm	0.6cm
Sample Volume	1.5-35µL	1-20µL
Reagent Volume	15-350µL	50-350µL
Reaction Volume	120-450µL	250-400µL

Differences
The Synermed IR-1200 can use smaller reagent and sample volumes than the Hitachi 717. The Synermed IR-1200 is smaller and weighs less than the Hitachi 717. The Synermed IR-1200 can use up to 4 reagents to perform an analysis while the Hitachi 717 can only use 2 reagents.

Items	Candidate Device: Synermed IR-1200 Glucose Reagent	Predicate Device: Synermed Glucose Reagent
Similarity/Difference		
Intended Use	For the quantitative measurement of glucose in serum.	For the quantitative measurement of glucose in serum and plasma.
Test Principle	Oxidase	Same
Sample Type	Serum	Serum and Plasma
Measuring Range	8-885 mg/dL	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-1200) as compared to the previously cleared Hitachi 717. The sponsor has chosen the representative analyte Glucose using serum as the representative sample matrix.

Analytical Performance

a. Precision/Reproducibility

Verification of precision on the Synermed IR-1200 was accomplished by implementing the study protocol laid out in CLSI document **EP05-A3.** Five concentrations of pooled patient serum were run for glucose. 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 glucose at each concentration. Additionally, the percentage of imprecision and total error was calculated. The results are displayed in the tables below.

Results:

Figure 1 – Glucose Mean, Standard Deviation & %CV for all 80 Results

	Within Run Precision		Total Precision	
Mean (mg/dL glucose)	**S.D. (mg/dL)**	**C.V. (%)**	**S.D. (mg/dL)**	**C.V. (%)**
44.6	0.25	0.5%	0.5	1.2%
120.7	1.35	1.1%	1.7	1.4%
180.8	1.74	0.9%	2.1	1.1%
375.2	0.6	0.1%	0.8	0.2%
626.03	0.6	0.09%	0.8	0.1%

b. Linearity/Reportable Range

Linearity studies were designed using **CLSI EP06-A**. Samples were prepared by intermixing a high serum pool with a low serum pool to obtain thirteen concentrations across the measuring range with four replicates at each concentration. The observed values were compared to the expected values and the results of linear regression are summarized below.

Linearity Results:

Measurand	Slope	Intercept	R^2	Sample Range Tested	Claimed Measuring Range
Glucose (mg/dL)	0.9928	1.3499	0.9999	6.5-900	8-885

Calibrators

The Synermed IR Cal II was previously cleared in K940571 and is traceable to NIST standard number 917-C; no modification was made.

c. Analytical Specificity

Interference studies were performed according to **CLSI EP07-A2**. Effects of common endogenous substances including bilirubin, hemoglobin, triglycerides and uric acid were evaluated by spiking serum pools with interferent at two analyte levels and at two concentrations of interferent. Additionally, common medications known to potentially affect the glucose assay were also tested at two analyte levels and at two concentrations of interferent. The sponsor defined significant interference as a bias of ≥±10% between the spiked and unspiked samples. Finally, any substance seen to interfere with the glucose assay was further studied using the dose-response procedure laid out on **CLSI EP07-A2**. Synermed will still reference in the product insert *Young, D.S., Effects of Drugs on Clinical Laboratory Tests, 5th ed. Vol.2 AACC Press, Washington, D.C., 2000*. The test results are summarized below:

Effects of common endogenous substances including conjugated bilirubin (0.76 and 20 mg/dL), unconjugated bilirubin (0.76 and 20mg/dL), hemoglobin (100 and 500 mg/dL), triglycerides (176.99 and 3274.34mg/dL) and uric acid (11.77 and 23.54mg/dL) were evaluated at two different glucose concentrations (80 mg/dL and 120 mg/dL) for interference. Furthermore, the following exogenous substances: ascorbic acid (1.22 and 6.02mg/dL), acetaminophen (20.11 and 200.18µg/mL), genatmicin (7.51 and 10.05µg/mL), ibuprofen (40.08 and 500.21µg/mL), L-dopa (0.41 and 1.24µg/ml/L), methyldopa (4.24 and 14.99µg/mL), N-acetylcysteine (0.08 and 0.25mg/dL), ofloxacin (8.78 and 17.5mg/L), salicyluric acid 0.2 and 0.6µg/mL), tetracycline (3.78 and 16.27µg.mL) were evaluated at two different glucose concentrations (80 mg/dL and 120 mg/dL) for interference. The sponsor defined non-significant interference when the bias between the tested and control samples are within +/-10%.

The sponsor identified ascorbic acid, methyldopa, levofloxacin, salicyluric acid, uric acid as interferants (see table).

Figure 2 – Results Summary, Dose-Response

The Synermed Glucose measurement procedure was evaluated for interference according to CLSI document **EP07-A2**. The following study results demonstrate that the following substances do not interfere with the Synermed Glucose assay at the highest concentration listed. A bias of <± 9.99% is considered non-significant interference.*

Interfering Substance	Highest Tested Concentration of Substance Without Significant Interference at Glucose Concentration = 80mg/dL	Highest Tested Concentration of Substance Without Significant Interference at Glucose Concentration = 120mg/dL
Ascorbic Acid	4.82mg/dL	4.82mg/dL
Methyldopa	12.31µg/mL	12.31µg/mL
Ofloxacin	8.78mg/L	8.78mg/L
Salicyluric Acid	0.5µg/mL	0.6µg/mL
Uric Acid	20.6mg/dL	20.6mg/dL

*Upper limit of 95% confidence interval.

Glucose

Significant interference from uric acid was observed when testing at both concentrations of glucose. Additionally, significant interference was seen with the following exogenous substances: ascorbic acid, methyldopa and salicyluric acid. See table below:

Figure 3 – Significant Interferents and Their Bias

Interferent	Interferent Concentration	% Bias Seen at Glucose 80mg/dL	% Bias Seen at Glucose 120mg/dL
Ascorbic Acid	6.02mg/dL	-11.7	-13.0
Methyldopa	14.99ug/mL	-10	-11.1
Salicyluric Acid	0.6ug/mL	-13.7	-8.7 *not significant
Uric Acid	23.54mg/dL	-10.7	-11.5

d. Detection Limit

Refer to the linearity data for the linearity results used to support the measuring range.
Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) were evaluated following **CLSI EP17-A**. Results are summarized in the table below.

Results:

Measurand	LoB	LoD	LoQ	Claimed Range
Glucose (Serum) (mg/dL)	2.8	3.65	8.0	8-885

e. Comparison Studies
Method comparison was performed according to **CLSI EP09-A3**, 115 samples for glucose were tested on the IR-1200 and Hitachi 717 chemistry analyzers. Thirteen percent (15 of the 115) samples studied were modified to cover the entire claimed measuring range. Modification of samples was obtained by intermixing patient serum pools with disparate results.

Results:

Test	Sample Type	Total # Samples	Sample Range Tested	Claimed Measuring Range	Slope	Intercept	Correlation Coefficient
Glucose mg/dL	Serum	115	15-885	8-885	0.988	-0.178	0.9994

16. Expected Values/Reference Range

The sponsor has provided the following Expected Values in labeling:
Glucose: 74-106 mg/dL

References:
Tietz NW, editor: Fundamentals of Clinical Chemistry, 6th ed., WB Saunders Co., PA, 2008.

17. 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.