July 10, 2018

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

Re: K181201
Trade/Device Name: Synermed ISE Reagents
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium test system
Regulatory Class: Class II
Product Code: JGS, CGZ, CEM
Dated: February 27, 2018
Received: May 11, 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 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)*
K181201

Device Name
Synermed ISE Reagents

Indications for Use *(Describe)*
The Synermed ISE Reagents are used for in-vitro diagnostic use to quantitate levels of Sodium, Potassium and Chloride in serum. This device is for use in clinical laboratories only. Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus and other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

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

K181201

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: July 2, 2018

4. Device Trade Name: Synermed ISE Reagents

5. Reagent Device Classification:

Pro Code	Classification Regulation	Classification Name	Device Class	Panel
JGS	862.1665	Sodium test system	Class II	75
CEM	862.1600	Potassium test system	Class II	75
CGZ	862.1170	Chloride test system	Class II	75

6. Identification of Predicates:

K-number	**Manufacturer**	**Trade Name**	**Method**
K952179	Synermed	Synermed ISE Reagents	Ion Selective Electrode

7. Device Description

The Synermed ISE reagents contain the following ingredients: Sodium Chloride, Potassium Chloride, Sodium Bicarbonate, Potassium Phosphate. The ISE buffer contains trlethanolamine preservatives 0.1M, phosphoric acid 0.3% and nonreactive preservatives. The ISE Mid-Standard contains sodium chloride 2.96mM, potassium chloride 0.12M, buffer and non-reactive preservatives. The ISE Reference contains 1M potassium chloride.

8. Substantial Equivalence

Items	**Candidate Device:** Synermed ISE Reagents K181201	**Predicate Device:** Synermed ISE Reagents K952179
Similarities		
Intended Use	**Quantitative Measurement of Sodium, Potassium and Chloride in serum**	**Same**
Environment	**Clinical Laboratory Use Only**	**Same**
Specimen	**Serum**	**Same**
Differences		
For use with	**Synermed IR-1200**	**Hitachi 717**

9. Intended Use

ISE Reagents
The Synermed ISE reagents are intended for the in vitro quantitative measurement of sodium, potassium, and chloride in serum. This device is for use in clinical laboratories only.
Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus and other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

10. Summary of Performance Testing

a. Precision/Reproducibility

Testing for Precision was accomplished by following the procedures and protocols outlined in the CLSI EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition, and in NCCLS EP15-A2 User Verification of Performance for Precision and Trueness; Approved Guideline – Second Edition

Results:
Data Examination – NCCLS document EP15-A2; Section 8 pp. 6-10.

Precision Data Analysis Section
Figure 1.1 - Mean, Standard Deviation & %CV for all 80 Results for Sodium

Sodium Precision Data Summary Table									
Target Concentration of Sodium in mEq/L	Actual Mean in mEq/L	Westgard %CV Within Run Requirement	Within Run %CV	Within Run SD	%CV Pass (Y/N)	Westgard %CV Run to Run Requirement	Run to Run %CV	Run to Run SD	%CV Pass (Y/N)
81	81.1	0.6	0.05	0.04	Y	0.7	0.04	0.03	Y
115	114.87		0.06	0.07	Y		0.05	0.06	Y
135	134.97		0.05	0.06	Y		0.04	0.06	Y
150	150.02		0.06	0.09	Y		0.05	0.07	Y
180	181.05		0.07	0.13	Y		0.07	0.12	Y

Figure 1.2 - Mean, Standard Deviation & %CV for all 80 Results for Potassium

Potassium Precision Data Summary Table									
Target Concentration of Potassium in mEq/L	Actual Mean in mEq/L	Westgard %CV Within Run Requirement	Within Run %CV	Within Run SD	%CV Pass (Y/N)	Westgard %CV Run to Run Requirement	Run to Run %CV	Run to Run SD	%CV Pass (Y/N)
1.5	1.49	4.6	0.52	0.01	Y	5.6	0.37	0.01	Y
3.0	2.98		0.22	0.01	Y		0.19	0.01	Y
5.8	5.79		0.12	0.01	Y		0.1	0.01	Y
7.5	7.49		0.11	0.01	Y		0.09	0.01	Y
10.0	10.04		0.58	0.06	Y		0.46	0.05	Y

Figure 1.3 - Mean, Standard Deviation & %CV for all 80 Results for Chloride

Chloride Precision Data Summary Table									
Target Concentration of Chloride in mEq/L	Actual Mean in mEq/L	Westgard %CV Within Run Requirement	Within Run %CV	Within Run SD	%CV Pass (Y/N)	Westgard %CV Run to Run Requirement	Run to Run %CV	Run to Run SD	%CV Pass (Y/N)
60	60.22	1.2	0.52	0.31	Y	1.5	0.48	0.29	Y
90	90.08		0.1	0.09	Y		0.07	0.07	Y
101	100.77		0.48	0.49	Y		0.43	0.43	Y
112	112		0.08	0.09	Y		0.06	0.06	Y
130	129.98		0.06	0.08	Y		0.05	0.48	Y

Acceptance Criteria

- The Within-Run Precision and Within-Laboratory Precision results should be less than the noted requirements from Westgard for percent imprecision.

b. Linearity/Reportable Range

Linearity

Testing for Linearity and Random Error was accomplished by following the procedures and protocols outlined in the NCCLS document EP6-A, Vol. 23, No. 16; Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

QC samples will be performed before daily testing **AND** with each run. QC results must be within the established range before testing can begin.

Linearity Results:

Measurand (in mmol/L)	Slope	Intercept	R^2	Sample Range Tested (in mmol/L)	Claimed Measuring Range (in mmol/L)
Sodium	0.9987	1.1021	0.9995	80-180	80-180
Potassium	1.0048	0.0237	0.9999	1.5-10	1.5-10
Chloride	0.9814	1.3911	0.9998	60-140	60-140

c. Analytical Specificity

Interfering Substances

Testing for Interference was accomplished by following the procedures and protocols outlined in the CLSI document EP07-A2; Interference Testing in Clinical Chemistry; Approved Guideline; Second Edition.

The following concentrations of endogenous substances were shown not to interfere with Sodium and Chloride.
Hemoglobin- 500mg/dL
Bilirubin (conjugated and unconjugated)- 342µmol/L
Triglycerides- 37mmol/L

The following concentrations of endogenous substances were shown not to interfere with Potassium.
Bilirubin (conjugated and unconjugated)- 342µmol/L
Triglycerides- 37mmol/L

Acceptance Criteria - Analyte Target Concentration ≤ ± 10% bias.
No bias was seen to be greater than 10%, thus all potential endogenous substance interference is considered to be within acceptable range. Hemolysis is a known contributing factor to abnormally high potassium levels, therefore hemolyzed samples should not be used. Other exogenous substances studies will be referenced to studies done by *Young, et al.*

d. Comparison Studies

Testing for Comparisons and Bias was accomplished by following the procedures and protocols outlined in the CLSI document EP09-A3; Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Third Edition.

Data Examination

a. Visual examination of the data is performed to look for outliers.
b. A correlation coefficient was calculated for each analyte.
c. Slope and Intercept were also calculated for each analyte.

Table 2.1 – IR-1200 and Hitachi 717 Comparison Study Data Summary

Sodium	
Correlation Coefficient	0.992246
Slope	0.990656
Intercept	0.943789
Potassium	
Correlation Coefficient	0.993021
Slope	0.985861
Intercept	-0.10291
Chloride	
Correlation Coefficient	0.993346
Slope	0.998305
Intercept	0.122558

11. 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.