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

June 1, 2017

TECO DIAGNOSTICS, INC.
HYUN BIN SONG
RESEARCH SCIENTIST
1268 NORTH LAKEVIEW AVENUE
ANAHEIM CA 92807

Re: K170200
Trade/Device Name: Carbon Dioxide Reagent Set
Regulation Number: 21 CFR 862.1160
Regulation Name: Bicarbonate/carbon dioxide test system
Regulatory Class: II
Product Code: KHS
Dated: April 26, 2017
Received: April 27, 2017

Dear Hyun Bin Song:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

k170200

Device Name

Carbon Dioxide Reagent Set

Indications for Use *(Describe)*

Teco Carbon Dioxide Reagent Set is a device which is intended for measurement of Carbon Dioxide level in human serum, in vitro diagnostic use only. Test results may provide information regarding the status in the assessment of acid-base balance of metabolic alkalosis or respiratory 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

1268 N. Lakeview Ave., Anaheim, CA 92807, U.S.A.
Phone: (714) 463-1111 Toll Free: 1-800-222-9880
Fax: (714) 463-1169
www.tecodiag.com

Section 5 - 510(k) SUMMARY

This Summary of 510(k) Safety and Effectiveness is being submitted in accordance with the requirements of 21 CFR § 807.92.

Owner's Name:
Teco Diagnostics, Inc.

Address and Contact information:
1268 North Lakeview Avenue
Anaheim, CA 92807
Phone: 714-463-1111
Fax: 714-463-1169

Contact:
Hyun Bin Song

Date Prepared:
January 20, 2017

1268 N. Lakeview Ave., Anaheim, CA 92807, U.S.A.
Phone: (714) 463-1111 Toll Free: 1-800-222-9880
Fax: (714) 463-1169
www.tecodiag.com

Section 5 - 510(k) SUMMARY

A. 510(k) Number:

k170200

B. Analytes:

Carbon Dioxide

C. Type of Test:

Enzymatic, quantitative assay

D. Applicant:

Teco Diagnostics, Inc.

E. Trade Name:

Carbon Dioxide Reagent Set

F. Common Name:

Enzymatic Method, Carbon Dioxide

G. Regulatory Information:

1. Regulation Classification section:

   Class II; 21 CFR § 862.1160-Bicarbonate/carbon dioxide test system

2. Product Code:

   KHS

3. Panel:

   75, Clinical Chemistry

1268 N. Lakeview Ave., Anaheim, CA 92807, U.S.A.
Phone: (714) 463-1111 Toll Free: 1-800-222-9880
Fax: (714) 463-1169
www.tecodiag.com

Section 5 - 510(k) SUMMARY

H. Intended Use:

1. Intended used:
   See Indications for Use below.

2. Indication(s) for Use:
   Teco Carbon Dioxide Reagent Set is a device which is intended for measurement of Carbon Dioxide level in human serum, in vitro use only. Test results may provide information regarding the status in the assessment of acid-base balance of metabolic alkalosis or respiratory acidosis.

3. Special conditions for use statement(s):
   This is an in vitro diagnostic test for professional use only.

4. Special instrument requirements:
   Not applicable

I. Device Description

Teco Carbon Dioxide Reagent Set is a single reagent kit. Reagent contains Good's buffer, phosphoenolpyruvate (PEP), phosphoenolpyruvate carboxylase (PEPC), malate dehydrogenase (MDH), magnesium ions, NADH analog, non-reactive stabilizer, preservative, and Buffer. Approximately 90% of carbon dioxide present in serum is in the form of bicarbonate. The measurement of bicarbonate is useful in the assessment of disturbances of acid-base balance resulting from metabolic or respiratory causes.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Pointe Scientific Inc., Carbon Dioxide Liquid Stable Reagent
2. Predicate K number(s):
   K070251
3. Compare with predicate:

Table 5.1 Teco Carbon Dioxide Reagent Set vs Pointe Scientific Inc., Carbon Dioxide Liquid Stable Reagent

	Teco Carbon Dioxide Reagent Set (Proposed Device)	Pointe Scientific Inc., Carbon Dioxide Liquid Stable Reagent (Predicate Device)
Manufacturer	Teco Diagnostics	Pointe Scientific Inc.

1268 N. Lakeview Ave., Anaheim, CA 92807, U.S.A.
Phone: (714) 463-1111 Toll Free: 1-800-222-9880
Fax: (714) 463-1169
www.tecodiag.com

Section 5 - 510(k) SUMMARY

Intended Use	This product is to be used for the quantitative determination of carbon dioxide in human serum by spectrophotometric analysis. For *in vitro* diagnostic use only.	Same
Measured Parameters	Bicarbonate	Same
Intended Specimen	Serum	Same
Test Methodology	Enzymatic; malate dehydrogenase and phosphoenolpyruvate carboxylase	Same
Instrument Mode	Automatic Instrument	Same
Linearity	Serum: 8.7 to 40.0 mmol/L	Serum: 2.0 to 40.0 mmol/L
Wavelength	405 nm	Same
Interferences	No interference was observed by conjugated bilirubin up to 30 mg/dL, total bilirubin up to 60 mg/dL, hemoglobin up to 1,000 mg/dL, triglycerides up to 2,000 mg/dL, ascorbic acid up to 6mg/dL, and intralipid up to 2,000 mg/dL.	No interference was observed by bilirubin up to 20.0 mg/dL, hemoglobin up to 400 mg/dL and lipemia (intralipid) up to 1,000 mg/dL.
Accuracy/Correlation (Serum)	$y = 0.9785x + 0.2636$, $R^2 = 0.9925$ and $R = 0.9962$	$y = 0.965x + 1.200$
Detection Limit (LoQ)	1.77 mmol/L (LoQ)	2.0 mmol/L
Storage Temperature	2- 8 ℃	Same

Teco Carbon Dioxide Reagent Set and the Pointe Scientific Carbon Dioxide Liquid Stable Reagent share the same technological characteristics including the testing parameters, test methodology, and storage.

K. Standard/Guidance Document Referred (if applicable):

1. CLSI EP5-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline Third Edition.
2. CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guidelines.
3. CLSI EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline Second Edition.

1268 N. Lakeview Ave., Anaheim, CA 92807, U.S.A.
Phone: (714) 463-1111 Toll Free: 1-800-222-9880
Fax: (714) 463-1169
www.tecodiag.com

4. CLSI EP9-A3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline Third edition.
5. CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures: Approve Guideline Second Edition.
6. CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline.

L. Test Principle:

The carbon dioxide in the human serum or serum based control sample reacts with phosphoenolpyruvate (PEP) in the presence of phosphoenolpyruvate carboxylase (PEPC) and magnesium to yield oxaloacetic acid (OAA) and phosphate. In the second reaction, in the presence of malate dehydrogenase (MDH), the reduced cofactor is oxidized by OAA. The reduced cofactor absorbs strongly at 405 nm, whereas its oxidized form does not. The difference in absorbance between the final reading and the blank, which is monitored at 405 nm/415 nm, is directly proportional to the total carbon dioxide concentration in the sample.

M. Performance Characteristics:

1. Analytical performance:
   a. *Precision/Reproducibility:*

In the accordance with CLSI EP5-A2 guideline, samples were tested in duplicate, 2 lots, and 2 runs per day for 20 days. The samples were unaltered human serums that were spiked with carbon dioxide concentrations and commercial serum based controls. The results were tabulated, and the data was analyzed for means, standard deviations (SDs), and percent coefficients of variation (%CVs). The precision result from one lot is summarized below.

Sample	Mean (mmol/L)	Repeatability		Within-Laboratory Precision	
		SD	%CV	SD	%CV
QC Level 1	30.6	0.1782	0.582	1.62	5.31
QC Level 2	20.5	0.7065	3.426	1.87	9.07
Serum Level 1	12.0	0.1275	1.065	0.69	5.75
Serum Level 2	26.6	0.1521	0.571	0.85	3.21
Serum Level 3	37.4	0.1949	0.521	0.59	1.58

1268 N. Lakeview Ave., Anaheim, CA 92807, U.S.A.
Phone: (714) 463-1111 Toll Free: 1-800-222-9880
Fax: (714) 463-1169
www.tecodiag.com

Section 5 - 510(k) SUMMARY

b. *Linearity/assay reportable range:*

Linearity studies of Teco Carbon Dioxide Reagent Set were performed in accordance with the guidelines set forth in CLSI EP6-A. Linearity was tested using two lots of reagent with unaltered human serum samples. The samples were prepared by mixing a diluted patient serum sample (2 mmol/L) and a spiked patient serum sample (64 mmol/L) in order to obtain 11 different concentrations. Each sample assay was tested in 3 replicates using TC-MATRIX analyzer. The reagent revealed that the assay is linear up to 64 mmol/L. The linearity of Carbon Dioxide (Enzymatic) was analyzed over a measured range from 8.70 to 40.0 mmol/L. As a result, the linear regression analyses were obtained as below:

$y= 1.0192x + 0.0351$; $R^2= 0.9993$

The reportable range of the CO_2 assay is 8.7 – 40.0 mmol/L

c. *Traceability, Stability, Expected values* (controls, calibrators, or methods)*:*

The CO_2 method is traceable to NIST SRM 351. The CO_2 assay is calibrated by comparing the change in absorbance of the unknown sample to the change in absorbance of the 30 mEq/L CO_2 standard (from Integrated Diagnostics Group). The CO_2 standard was previously cleared under K936245.

It is recommended using an aqueous CO_2 standard (30 mmol/L) or an appropriate serum calibrator. To monitor the reliability of results, it is recommended using two levels of control sera with known CO_2 values to be run along with patient sample.

The stability claim was verified using an accelerated stability protocol. Accelerated stability of the CO_2 reagent was determined based on Arrehnius Model equation. Based on the study, accelerated stability of the CO_2 reagent was demonstrated to be at least 21 months if the CO_2 reagent is tightly capped and stored at 2-8°C. Reagents in unopened vials are stable at 2-8°C until the expiry date printed on the label. The assay was calibrated using a valid calibrator and measured as sample in duplicates. The verification of the real time stability is on going.

d. Quality Control materials

Users are instructed in the labeling to use quality control samples at least once a day and after each calibration and every time a new bottle of reagent is used. It is recommended to use at least two levels (low and high) of controls. Available controls are Lyphochek® Unassayed Chemistry Control (Human)

1268 N. Lakeview Ave., Anaheim, CA 92807, U.S.A.
Phone: (714) 463-1111 Toll Free: 1-800-222-9880
Fax: (714) 463-1169
www.tecodiag.com

Section 5 - 510(k) SUMMARY

Levels 1 and 2 (Lot number: 27661 and 27662) and were previously cleared under K882486.

e. *Detection limit:*

Detection limit studies have been carried out in accordance with CLSI EP17-A2 guideline. Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantification (LoQ) studies were performed on two lots of reagents tested on one TC-MATRIX analyzer (K073370). For the LoB and LoD studies, four (4) samples were tested in five (5) replicates over 3 days. For LoQ study, five (5) samples were tested in three (3) replicates over 3 days. The LoD pools consisted of 4 separate pools, and LoQ pools consisted of 5 separate pools near the current bottom of the serum assay ranges. The 9 LoD / LoQ serum pools were prepared by diluting patient serum with artificial serum. The LoB pool consisted of artificial serum base matrix with no carbon dioxide added. LoQ is the lowest concentration that can be detected with ≤ 10%CV. LoB, LoD and LoQ results are summarized in the following table:

Analyte	LoB	LoD	LoQ
CO_2 (mmol/L)	0.92	1.5	1.77

f. *Analytical specificity:*

Interference studies have been carried out in accordance with CLSI EP7-A2 guideline. Two (2) different concentrations of sodium bicarbonate (20 mmol/L and 35 mmol/L) human serum samples were used to evaluate interference testing using one TC-MATRIX analyzer (K073370) and two reagent lots. Pooled human serum samples with added potential interferents were tested in replicates of ten (10) and compared to a sample without interferent. Teco Carbon Dioxide Reagent Set was evaluated for interferences tested by bilirubin (Total and Conjugated), hemoglobin, triglyceride, ascorbic acid, and intralipid in serum samples. The following substances demonstrated no significant bias as defined as ±10% difference from the control results.

Interferent	concentration at which no significant interference was observed
Hemoglobin	1,000 mg/dL
Total Bilirubin	60 mg/dL
Conjugate Bilirubin	30 mg/dL
Triglycerides	2,000 mg/dL
Intralipid	2,000 mg/dL
Ascorbic Acid	6 mg/dL

1268 N. Lakeview Ave., Anaheim, CA 92807, U.S.A.
Phone: (714) 463-1111 Toll Free: 1-800-222-9880
Fax: (714) 463-1169
www.tecodiag.com

Section 5 - 510(k) SUMMARY

g. *Assay cut-off:*
Not applicable

2. Comparison studies:

a. *Method comparison*
Serum CO_2 correlation determination of the Pointe Scientific Inc. Carbon Dioxide Reagent (X) and Teco Carbon Dioxide Reagent Set (Y) was performed by using 176 patient serum samples ranging from 8.7 to 37.2 mmol/L of CO_2 on TC-MATRIX analyzer (K073370), to obtain the following results

$y = 0.9785x + 0.2636$ mmol/L, $R^2 = 0.9925$ and $R=0.9962$.

b. *Matrix comparison*
Not applicable.

3. Clinical studies:
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
Reference interval of normal range (Serum): 23 – 33 mmol/L

The provided normal ranges are derived from Tietz NW. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, PA: WB Saunders Company; 1995:110-111.

N. Conclusion:

The performance characteristics of the Carbon Dioxide Reagent Set were verified by comparison, precision, linearity, detection limit, specificity and interference, shelf life, and stress studies. Testing results indicate that the Carbon Dioxide Reagent Set performs satisfactorily when used appropriately, as outlined in the package insert. The result of performance studies demonstrates a substantial equivalency on performance between Teco Carbon Dioxide Reagent Set and the predicate device, Pointe Scientific Liquid Stable Reagent.

In summary, the submitted information in this premarket notification is complete and supports a substantial equivalence decision.