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

July 21, 2017

TECO DIAGNOSTICS, INC.
XIAOYAN HU
RESEARCHER
1268 NORTH LAKEVIEW AVENUE
ANAHEIM CA 92807

Re: K161527
Trade/Device Name: Teco Creatinine Enzymatic Reagent Kit
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: II
Product Code: JFY
Dated: July 13, 2017
Received: July 14, 2017

Dear Xiaoyan Hu:

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)*
K161527

Device Name
Teco Creatinine Enzymatic Reagent Kit

Indications for Use *(Describe)*
Creatinine Enzymatic Reagent Kit is a device which is intended for measurement of creatinine level in human serum, in vitro diagnostic use only. Test results may provide information regarding the status of kidney function and the diagnosis of renal diseases, and also serve as a component of several calculations for determination or estimation of creatinine clearance or glomerular filtration rate (GFR).

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.tecodiagnostics.com

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:
Xiaoyan Hu

Date Prepared:
July 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.tecodiagnostics.com

510(k) SUMMARY

A. 510(k) Number:
K161527

B. Analytes:
Creatinine

C. Type of Test:
Enzymatic, quantitative

D. Applicant:
Teco Diagnostics, Inc.

E. Trade Name:
Teco Creatinine Enzymatic Reagent Kit

F. Common Name:
Enzymatic Method, Creatinine

G. Regulatory Information:

1. Regulation Classification section:
Class II: 21 CFR § 862.1225-Creatinine test system
2. Product Code:
JFY
3. Panel:
75, Clinical Chemistry

H. Intended Use:

1. Indication(s) for use:
Creatinine Enzymatic Reagent Kit is a device which is intended for measurement of creatinine level in human serum, in vitro diagnostic use only. Test results may provide information regarding the status of kidney function and the diagnosis of renal diseases, and also serve as a component of several calculations for determination or estimation of creatinine clearance or glomerular filtration rate (GFR).
2. Special conditions for use statement(s):
This is an in vitro diagnostic test for prescription use only.
3. Special instrument requirements:
TC-MATRIX analyzer

I. Device Description

Creatinine Enzymatic Reagent Kit is a dual reagent kit. Reagent one contains Good's buffer, creatine amidinohydrolase, sarcosine oxidase and ESPMT (3-(N-Ethyl-3-methylanilino) propanesulfonic acid sodium salt). Reagent two contains Good's buffer, creatinine amidohydrolase, Peroxidase and 4-aminoantipyrine.

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.tecodiagnostics.com

510(k) SUMMARY

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Stanbio Creatinine LiquiColor test system
2. Predicate K number(s):
   K050283
3. Compare with predicate:

Table 5.1 Creatinine Enzymatic Reagent Kit vs Stanbio Creatinine LiquiColor test system

	Teco Creatinine Enzymatic Reagent Kit	Stanbio Creatinine LiquiColor test system
Intended Use	For the quantitative determination of creatinine.	Same
Intended Specimen	Serum	Serum and urine
Test Methodology	Enzymatic	Same
Linearity	Serum: 0.37- 5.06 mg/dL	Serum: 0.04 to 5.1 mg/dL Urine: 0.04 to 200 mg/dL
Wavelength	Primary: 546 nm Secondary: 670 nm	546 nm
Accuracy/Correlation (Serum)	y = 1.004x+ 0.0379 R^2 = 0.9986	y = 0.9993x+0.0018 R = 0.9999
Storage	2- 8 °C	Same

K. Guideline 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 Guideline.
3. CLSI EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline Second edition.
4. CLSI EP9-A3, Method 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.
7. CLSI EP28-A3C, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline Third 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.tecodiagnostics.com

510(k) SUMMARY

L. Test Principle:

Creatinase in Reagent 1 hydrolyzes existing creatine in a sample to sarcosine and urea. Sarcosine is oxidized by sarcosine oxidase to glycine and formaldehyde and hydrogen peroxide. This hydrogen peroxide is reduced to water soon. Ceatininase in Reagent 2 hydrolyzes creatinine in sample to creatine. By the same reaction steps above, the hydrogen peroxide from creatinine reacts with 4-aminoantipyrine and ESPMT in the presence of peroxidase to yield a quinoneimine dye. The change in absorbance at 546 nm is proportional to the creatinine concentration in sample.

M. Performance Characteristics:

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies were performed based on upon the guidelines set forth in CLSI EP5-A. Intra-assay Precision was performed by assaying three serum pools at three concentrations over 20 operating days, on a single instrument at a single site and with two lots of reagents. Assay runs were performed twice per day and each sample was tested in triplicates. Results of the precision studies were summarized below:

LOT: 080201

Sample Description	Mean (mg/dL)	Repeatability		Within- Laboratory Precision	
		SD	CV%	SD	CV%
Patient Pool 1	0.89	0.008353	0.93	0.01761	1.98
Patient Pool 2	1.52	0.01323	0.87	0.03316	2.18
Patient Pool 3	3.09	0.02800	0.90	0.03361	1.08

LOT: 080202

Sample Description	Mean (mg/dL)	Repeatability		Within- Laboratory Precision	
		SD	CV%	SD	CV%
Patient Pool 1	0.88	0.00922	1.05	0.02009	2.28
Patient Pool 2	1.51	0.01039	0.69	0.03402	2.25
Patient Pool 3	3.04	0.02736	0.90	0.03682	1.21

b. Linearity/assay reportable range:

Linearity studies were performed based on upon the guidelines set forth in CLSI EP6-A. Linearity was performed by preparing samples from patient serum pools at a low creatinine concentration and a high concentration. Eleven samples in all were assayed in duplicates for each reagent lot. The expected values were plotted against

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.tecodiagnostics.com

510(k) SUMMARY

the observed values and a linear regression line from one of the reagent lots fitted with the following regression equation:

Expected Value (mg/dL)	Observed Value (mg/dL)
0.37	0.374
0.94	0.946
1.50	1.518
2.06	2.090
2.71	2.663
3.31	3.235
3.83	3.807
4.38	4.379
4.90	4.951
5.49	5.523
6.12	6.095

Considering these testing concentrations from Linearity study and Method Comparison study, and the assay range of predicate device (0.04 – 5.1 mg/dL), the claimed measuring range for Teco Creatinine Enzymatic Reagent Kit is 0.37- 5.06 mg/dL. The regression is $y = 0.9992x + 0.0007$, $R^2 = 0.9983$.

c. *Traceability, Stability, Expected values*:
The stability claim was verified using an accelerated stability protocol. Real-time testing was conducted. The study results are summarized below:

Storage Conditions		Claimed stability
Closed-vial	37 ± 2 °C	20 days
Open-vial	2 - 8°C, 20-30% humidity	60 days
Real-time, closed-vial	2 - 8°C, 20-30% humidity	Pending

Traceability
The Teco chemistry calibrator values were obtained by multi determinations performed by Teco Diagnostics. The assigned value is the median of all values obtained. The assigned value of the calibrator is traceable to NIST reference material (SRM 967).

d. *Detection limit:*
Limit Of Blank (LoB):
The study was determined following CLSI EP17-A2 as a guideline. Four diluted real pooled serum samples were tested in the limit of blank study. Fifteen replicates

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.tecodiagnostics.com

510(k) SUMMARY

of each sample were assayed using TC-MATRIX instrument and two reagent lots, with the total number of measurements being 60 for each lot.
Based upon the studies conducted for LoB, the data were assessed using the nonparametric data analysis option, and the following results were obtained: 0.00 mg/dL.

Limit Of Detection (LoD):
The LoD study was determined following CLSI EP17-A2 as a guideline. In the Limit Of Detection the serum was determined by using two reagent lots. Four diluted serum samples of 100 times, 50 times, 33 times and 25 times were assayed 15 times for each sample (N = 60) on the TC-MATRIX instrument. Based upon the studies conducted for LoD and the reported LoB determined above, this gave result of 0.01 mg/dL.

Limit Of Quantitation (LoQ):
The LoQ study was determined following CLSI EP17-A2 as a guideline. For LoQ determination, four low concentration samples were prepared by native serum sample pools and assayed fifteen times each (N = 60). The CV% and the SD at each tested concentration were calculated. The LoQ accuracy goal is within 20% CV.

Results of Summary:

	LoB	LoD	LoQ
Value (mg/dL)	0.00	0.01	0.10

e. *Analytical specificity:*
Testing for interfering substances was based on CLSI EP7-A2. Testing was performed with two different clinically relevant concentrations of creatinine (1.50 and 5.00 mg/dL). Samples with increasing amounts of potential interferents were tested in triplicate and compared to a control sample without the interferent. The concentrations of substances that demonstrated no significant interference (⩽10%) are listed below:

Interference Substance	Highest concentration tested with no significant interference (≤10%)
Unconjugated Bilirubin	20 mg/dL
Conjugated Bilirubin	16.7 mg/dL
Hemoglobin	500 mg/dL
Triglycerides	2500 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.tecodiagnostics.com

510(k) SUMMARY

Ascorbic Acid	20 mg/dL
Creatine	6.0 mg/dL
Glucose	1000 mg/dL
Acetaminophen	20 mg/dL
Nitrofurantoin	400 ug/dL
Uric acid	25 mg/dL
Dopamine	90.0 ug/dL
Methyldopa	0.10 mg/dL
L- Dopa	0.06 mg/dL
Calcium dobesilate	1 mg/dL

The following table shows the substances which did interfere with Teco Creatinine Enzymatic Reagent Kit. The concentrations of interfering substance that demonstrated a significant interference are listed below:

Interference Substance	Concentration of Substance at which Interference was observed
Conjugated Bilirubin	24.95 mg/dL
Triglycerides	3000 mg/dL
Creatine	8.0 mg/dL
Methyldopa	0.45 mg/dL
L- Dopa	0.11 mg/dL
Calcium dobesilate	3 mg/dL

A summary of the interferents with effects is found in the labeling.

2. Comparison studies:

Method comparison

The performance of the Creatinine Enzymatic Reagent Kit was compared with the Stanbio Creatinine LiquiColor test system on TC-MATRIX analyzer. Study performed according to CLSI EP9-A3 using 98 serum samples covering the measuring range with values from predicate and the result from the linearity study in M 1.b. The linear regression is summarized as $y=1.004x+0.0379$, $R^2 = 0.9986$.

Based on the detection limits determined in this study, the result from the method comparison study in M 2.a. and the result from the linearity study in M 1.b., the labeling claims a measuring range of 0.37 to 5.06 mg/dL.

3. Expected values/Reference interval:

The expected reference interval is derived from: Larsen K. Clin Chem Acta 41:209, 1972. The reference interval for Creatinine was verified using CLSI guideline EP28-

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.tecodiagnostics.com

510(k) SUMMARY

A3 by conducting a small study using human serum samples from 20 healthy male donors and 20 healthy female donors, from 20 to 65 years old. The samples were assayed on TC-MATRIX analyzer. All results from the total 40 healthy donors were found to be within the reported reference range. The Reference Interval for the study for Teco Creatinine Enzymatic Reagent Kit shows:

	Men	Women
Serum (mg/dL)	0.9 - 1.5	0.7 - 1.4

N. Conclusion:

The performance characteristics of Teco Creatinine Enzymatic Reagent Kit were verified by comparison, precision, linearity, detection limit, specificity and interference, shelf life, and stress studies. Testing results indicate that Teco Creatinine Enzymatic Reagent Kit performs satisfactorily when used appropriately, as outlined in the package insert. The result of performance studies demonstrates a substantial equivalency on performance between Teco Creatinine Enzymatic Reagent Kit and the predicate device, Stanbio Creatinine LiquiColor test system.