TECO DIAGNOSTICS

K101673

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

FEB - 4 2011

005 - 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

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

Contact:
Limin Lin, Ph. D.

Date Prepared:
June 14, 2010

TECO DIAGNOSTICS

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

005 - 510(k) SUMMARY

A. 510(k) Number:

B. Analytes:
Urinary Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes.

C. Type of Test:
Semi-quantitative

D. Applicant:
Teco Diagnostics, Inc.

E. Trade Name:
Teco Diagnostics Uritek TC-101 Urine Analyzer
Urine Reagent Strip (URS) 10

F. Common Name:
Automated Urinalysis System

G. Regulatory Information:

1. Regulation Classification section:
   Class I: 21 CFR § 862.2900 –Automated urinalysis system.
   Class I: 21 CFR § 864.7675 –Leukocyte peroxidase test.
   Class I: 21 CFR § 862.1510 –Nitrite (nonquantitative) test system.
   Class I: 21 CFR § 862.1785 –Urinary Urobilinogen (nonquantitative) test system.
   Class I: 21 CFR § 862.1645 –Urinary protein (nonquantitative) test system.
   Class I: 21 CFR § 862.1550 –Urinary pH (nonquantitative) test system.
   Class II: 21 CFR § 864.6550 –Occult blood test.
   Class I: 21 CFR § 864.9320 –Copper sulfate solution for specific gravity determinations
   Class I: 21 CFR § 862.1435 –Ketones (nonquantitative) test system.
   Class I: 21 CFR § 862.1115 –Urinary Bilirubin (nonquantitative) test system.
   Class II: 21 CFR § 862.1340 –Urinary glucose (nonquantitative) test system.

2. Product Code:
   KQO
   Subsequent Codes: CDM, CEN, JIL, JIN, JIO, JIR, JJB, JMT, LJX, KSL
3. Panel:
   Clinical Chemistry

TECO DIAGNOSTICS

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

005 - 510(k) SUMMARY

H. Intended Use:

Indication(s) for use:

The Uritek TC-101 urine analyzer is an automated, bench top instrument which is intended for prescription, in vitro diagnostic use only. The instrument is intended to be used together with the Urine Reagent Strips (URS) 10 as a system for the semi-quantitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and bacteriuria.

I. Device Description

The Uritek TC-101 Urine Analyzer is a portable easy to use instrument which reads Teco Urine Reagent Strips (URS) 10 for testing in the clinical laboratory. The TC-101 can determine the intensity of different colors on the reagent strip test area. It does this by irradiating the test area with light and detecting the reflectance of different wavelengths using an integrated sphere photo-detector. This photo-detector is filtered to measured wavelengths of 525nm, 550nm, 620nm, and 720nm by the integrated sphere. Results are calculated by a reflection rate which is a percentage of the total reflectance of the testing wavelength and are printed automatically.

The Uritek TC-101 reports semi-quantitative assays for 10 urine analytes (glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocytes). Reagent strip results are automatically displayed on the screen in one minute. A printed hardcopy can also be created either from the results screen or recalled from memory. The analyzer features a display, internal printer, a serial computer interface and an electrical outlet. Communication between the operator and the analyzer is made through the display using the arrows and 'yes' or 'no' buttons on the front of the analyzer.

The Urine Reagent Strips (URS) 10 are urine test strips of which glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocyte reagent pad are affixed onto the firm plastic strips. The reagent pad areas are bibulous material saturated with chemically active substances, then dried and affixed to the plastic strip with double-sided adhesive. URS 10 provide tests for the semi-quantitative determination of glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite and leukocytes in urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and bacteriuria.

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

005 - 510(k) SUMMARY

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Bayer Clinitek Status Analyzer
   Bayer Multistix 10 SG Reagent Strips for Urinalysis
2. Predicate K number(s):
   k031947
3. Compare with predicate:

Table 5.1 Uritek TC-101 vs Clinitek Status

Similarities		
Item	Device	Predicate
Testing Parameters	glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocytes	Same
Print out	Fixed Head Printer- Roll stock	Same
Calibration Method	Dark current, white reflectance strip	Same
Power	Input 100-240 V ± 20% and 45-65 Hz, output + 9V	Same
Differences		
Item	Device	Predicate
Entered Parameter	Urine Color and Clarity, Patient ID	Same plus Operator ID
Dimensions	Width 8.5 in Depth 6.4 in Height 4.25 in	Width 6.7 in Depth 10.7 in Height 6.2 in
Weight	5.21 lbs	3.65 lbs

The Uritek TC-101 and the Clinitek Status share the same technological characteristics including the testing parameters, print out, calibration method, and power requirements. They only differ in their dimensions, weight, and entered parameter.

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

005 - 510(k) SUMMARY

Table 5.2 Urine Reagent Strips 10 vs Multistix 10 SG

	Similarities	
Item	URS 10	Multistix 10 SG
Intended Use	Intended for prescription, in vitro diagnostic use only.	Intended for prescription, in vitro diagnostic use only.
Intended Specimen	Urine	Urine
Materials Provided	Plastic strips affixed with reagent pads	Plastic strips affixed with reagent pads
Glucose Methodology	Based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with potassium iodide chromogen to oxidize the chromogen to colors ranging from blue-green to greenish-brown through brown and dark brown.	Same
Bilirubin Methodology	Based on the coupling of Bilirubin with a diazotized dichloroaniline in a strongly acid medium. The colors range from light tan to reddish-brown.	Same
Ketone Methodology	Based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige or buff-pink color for a "Negative" reading to pink and pink-purple for a "Positive" reading.	Same
Specific Gravity Methodology	Based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark blue or blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration.	Same

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

005 - 510(k) SUMMARY

Blood Methodology	Based on the pseudoperoxidase action of hemoglobin and erythrocytes which catalyzes the reaction of 3,3',5, 5'-tetramethyl-benzidine and buffered organic peroxide. The resulting colors range from orange to yellow-green and dark green. Very high blood concentration may cause the color development to continue to dark blue.	Same
pH Methodology	Based on the well known double pH indicator method, where bromothymol blue and methyl red give distinguishable colors over the pH range of 5-9. The colors range from red-orange to yellow and yellow-green to blue-green.	Same
Protein Methodology	Based on the protein error-of-indicator principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for a "Negative" reaction to yellow-green and green to blue-green for a "Positive" reaction.	Same
Urobilinogen Methodology	Based on a modified Ehrlich reaction in which *p*-diethylaminobenzaldehyde reacts with urobilinogen in a strongly acid medium. Colors range from light pink to bright magenta.	Same
Nitrite Methodology	This test depends on the conversion of nitrate to nitrite by the action of Gram-negative bacteria in the urine. The nitrite reacts with *p*-arsanilic acid to from a diazonium compound in an acid medium. The diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h) quinolin to produce a pink color.	Same

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

005 - 510(k) SUMMARY

Leukocyte Methodology	Based on the action of esterase present in leukocytes, which catalyzes the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with a diazonium salt to produce a beige-pink to purple color.	Same

The Urine Reagent Strips 10 and Multistix 10 SG share the same characteristics including Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocyte methodologies.

K. Test Principle:

Glucose: This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the reaction in which glucose is oxidized to produce gluconic acid and hydrogen peroxide. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with potassium iodide chromogen in which the chromogen is oxidized to different colors ranging from blue-green to greenish-brown through brown and dark brown.

Bilirubin: This test is based on the coupling of bilirubin with a diazotized dichloroaniline in a strongly acid medium. Varying bilirubin levels will produce light tan to reddish-brown color propotional to its concentration in urine.

Ketone: This test is based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige or buff-pink color for a "Negative" reading to pink and pink-purple for a "Positive" reading.

Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark blue or blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration.

Blood: This test is based on the pseudoperoxidase action of hemoglobin and erythrocytes which catalyzes the reaction of 3,3',5, 5'-tetramethyl-benzidine and buffered organic peroxide. The resulting colors range from orange to yellow-green and dark green. Very high blood concentration may cause the color development to continue to dark blue.

pH: This test is based on the well known double pH indicator method, where bromothymol blue and methyl red give distinguishable colors over the pH range of 5-9. The colors range from red-orange to yellow and yellow-green to blue-green.

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

005 - 510(k) SUMMARY

Protein: This test is based on the protein error-of-indicator principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for a "Negative" reaction to yellow-green and green to blue-green for a "Positive" reaction.

Urobilinogen: This test is based on a modified Ehrlich reaction in which *p*-diethylaminobenzaldehyde reacts with urobilinogen in a strongly acid medium. Colors range from light pink to bright magenta.

Nitrite: This test depends on the conversion of nitrate to nitrite by the action of Gram-negative bacteria in the urine. The nitrite reacts with *p*-arsanilic acid to from a diazonium compound in an acid medium. The diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h) quinolin to produce a pink color.

Leukocytes: This test is based on the action of esterase present in leukocytes, which catalyzes the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with a diazonium salt to produce a beige-pink to purple color.

L. Clinical Performance Characteristics:

The clinical studies were performed at Point-of-Care sites using Teco Diagnostics' Uritek TC-101 and Urine Reagent Strips 10 versus Bayer's Clinitek Status with Multistix 10 SG. Clinical data were presented to evaluate clinical accuracy of results.
Clinical study results indicate that the intended users were able to obtain comparable testing data when using the Uritek TC-101 with Urine Reagent Strips 10 and the legally marketable Bayer Clinitek Status with Multistix 10 SG.

M. Conclusion:

The performance characteristics of the Uritek TC-101 with the Urine Reagent Strips 10 were verified by method comparison, precision, linearity, detection limit, specificity, shelf life, and stress studies. Testing results indicate that the Uritek TC-101 and Urine Reagent Strips 10 perform satisfactorily when used appropriately, as outlined in the package insert.

The clinical studies results demonstrate a substantial equivalency on performance between Teco Diagnostics' Uritek TC-101 with Urine Reagent Strips 10 and the predicate device, Bayer Clinitek Status with Multistix 10SG.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB 04 2011

Teco Diagnostics
c/o Dr. K.C. Chen
1268 North Lakeview Avenue
Anaheim, CA 92807

Re: k101673
Trade Name: Uritek TC-101 with Urine Reagent Strips (URS) 10
Regulation Number: 21 CFR §862.1340
Regulation Name: Urinary glucose (non-quantitative) test system.
Regulatory Class: Class II
Product Code: JIL, CDM, JJB, JIN, JIR, JMT, LJX, CEN, JRE, KQO, JIO
Dated: December 09, 2010
Received: December 10, 2010

Dear Dr. Chen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (If Known): k101673

Device Name: Uritek TC-101 with Urine Reagent Strips (URS) 10

Indications for Use:

The Uritek TC-101 urine analyzer is an automated, bench top instrument which is intended for prescription, in vitro diagnostic use only. The instrument is intended to be used together with the Urine Reagent Strips (URS) 10 as a system for the semi-quantitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and bacteriuria.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101673