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

TECO DIAGNOSTICS, INC.
AQUIL MERCHANT
RESEARCH SCIENTIST
1268 N. LAKEVIEW AVE.
ANAHEIM CA 92807

July 22, 2016

Re: k160372
Trade/Device Name: Uritek TC-201 Urine Chemistry Test System
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: II
Product Code: JIL, JIO, KQO, LJX, JRE, CEN, JMT, JIR, JIN, CDM, JJB
Dated: June 1, 2016
Received: June 2, 2016

Dear Mr. Merchant:

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)*
k160372

Device Name
Uritek TC-201 Urine Chemistry Test System

Indications for Use *(Describe)*
The Uritek TC-201 Urine Chemistry Test System consists of the Uritek TC-201 Urine Chemistry Analyzer and the Teco Diagnostics Urine Reagent (URS-10) Strips. The Uritek TC-201 urine analyzer is an automated, bench top instrument which is intended for point-of-care, in vitro diagnostic use only and is intended to be used together with the Teco Diagnostics Urine Reagent (URS-10) Strips as a system for semi-quantitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in urine. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections and liver function.

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

I. SUBMITTER

Applicant Information:
Teco Diagnostics, Inc.
1268 North Lakeview Avenue
Anaheim, CA 92807
Phone: 714-463-1111
Fax: 714-463-1169

Contact Person: Aquil Merchant, M.S.
Research Scientist
Email: aquil@tecodiagnostics.com | Web: http://www.tecodiagnostics.com

Date Prepared: July 20th, 2016

II. DEVICE

Device Name:
Uritek TC-201 Urine Chemistry Test System

Common Name:
Automated Urinalysis System, Urinary Test System
The system consists of the Uritek TC-201 Urine Analyzer and the Teco Diagnostics Urine Reagent (URS-10) Strips (k970250).

Regulatory Information:

Panel:
Clinical Chemistry

Regulation section	Code	Test	Classification
21 CFR § 862.1340	JIL	Urinary Glucose (nonquantitative) Test System	II
21 CFR § 864.6550	JIO	Occult Blood Test	II
21 CFR § 862.2900	KQO	Automated Urinalysis System	I
21 CFR § 864.7675	LJX	Leukocyte Peroxidase Test	I
21 CFR § 862.2800	JRE	Refractometer for clinical use	I
21 CFR § 862.1550	CEN	Urinary pH (nonquantitative) Test System	I
21 CFR § 862.1510	JMT	Nitrite (nonquantitative) Test System	I
21 CFR § 862.1645	JIR	Urinary Protein or Albumin (nonquantitative) Test System	I

510(k) SUMMARY

21 CFR § 862.1435	JIN	Ketones (nonquantitative) Test System	I
21 CFR § 862.1785	CDM	Urinary Urobilinogen (nonquantitative) Test System	I
21 CFR § 862.1115	JJB	Urinary Bilirubin and its conjugates (nonquantitative) Test System	I

III. PREDICATE DEVICE

Siemens (formally Bayer) Clinitek Status Plus Analyzer
SIEMENS HEALTHCARE DIAGNOSTICS
2 Edgewater Dr.
Norwood, MA 02062
510(k) Number: k091216

IV. DEVICE DESCRIPTION

The Uritek TC-201 Urine Analyzer (TC-201) is a portable easy to use instrument which reads Teco Diagnostics' Urine Reagent (URS-10) Strips for testing in the clinical laboratory. The analyzer 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 photodiode. 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-201 Urine Analyzer reports semi-quantitative assays for Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in urine. 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 user interface touch screen on the front surface of the instrument. 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 Urine Reagent Strips (URS-10) for Urinalysis are firm plastic strips to which ten different reagent pads are affixed. The reagent pad areas are bibulous material saturated with chemically active substances, then dried and affixed to the plastic strip with double-sided adhesive. The Teco Urine Reagent (URS-10) Strips provide tests for the semi-quantitative determination of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes in urine.

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510(k) SUMMARY

V. INDICATIONS FOR USE

The Uritek TC-201 Urine Chemistry Test System consists of the Uritek TC-201 Urine Chemistry Analyzer and the Teco Diagnostics Urine Reagent (URS-10) Strips. The Uritek TC-201 urine analyzer is an automated, bench top instrument which is intended for point-of-care, in vitro diagnostic use only and is intended to be used together with the Teco Diagnostics Urine Reagent (URS-10) Strips as a system for semi-quantitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in urine. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections and liver function.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Uritek TC-201 Urine Analyzer and the Clinitek Status Plus Analyzer, a POC device currently sold in the US market, share the same technological characteristics including the analytical method, testing parameters, calibration method, and power requirements. They only differ in battery, language option, their memory size, dimensions and weight. The comparison is summarized in the following table:

	Proposed Device	**Predicate**
Trade Name	Uritek TC-201 Urine Analyzer	Clinitek Status Plus Urine Analyzer
Intended Use	The device is intended to be used together with the Teco Diagnostics Urine Reagent (URS-10) Strips as a system for the semi-quantitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes in urine.	The device is intended to be used together with Clinitek Multistix 10 SG Strips as a system for the semi-quantitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes in urine.
Methodology	Reflectance Photometer	Reflectance Photometer
Specimen Type	Urine	Same
Chemistry Strips	Teco Diagnostics Urine Reagent (URS-10) Strips	Clinitek Multistix 10 SG

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Analytical Method	The analyzer measures the intensity of the light reflected from the reagent pads of a urinalysis	Same
Testing Parameters	Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes	Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes
Calibration Method	Self-calibration with the white reflective check area located at the back of the test strip bed	Same
Operating interface	Touch Screen	Same
Entered Parameter	Urine Color and Clarity, Patient ID and Operator ID	Same
Printer	Built-in thermal printer	Same
PC Port	Standard RS232 Serial Port, USB Port	Same
Power	Input 100-240 VAC ± 20% and 45-65Hz, output + 9V	Same
Battery Powered Operation	None	6 AA non-rechargeable alkaline batteries
Line Leakage Current	<0.5mA	<0.5mA
Analyzer Operating Conditions	18-30°C (64-86°F); 18%-80% Relative Humidity (non-condensing)	Same
Memory	Store up to 2000 test results	Store up to 950 test results
Display Language	English, Spanish, Chinese	English, Spanish
Screen Display	Color	Mono-tone
Dimensions	Width 7.25 in Depth 10.5 in Height 6.5 in	Width 6.7 in Depth 10.7 in Height 6.2 in
Weight	1.88kg (4.14 lbs)	1.66kg (3.65 lbs)

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510(k) SUMMARY

The Teco Diagnostics Urine Reagent (URS-10) Strips and Clinitek Multistix 10 SG Strips share the same characteristics including Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocyte methodologies.

VII 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 dichioroaniline in a strongly acid medium. Varying bilirubin levels will produce light tan to reddish brown color proportional 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.

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.

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510(k) SUMMARY

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 diazoniumn 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 diazoniumn salt to produce a beige-pink to purple color.

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VIII. SUMMARY OF PERFORMANCE TESTING

1. Software

The software development, verification, and validation were performed according to the Food and Drug Administration's guidance document. The contents of the software testing for this submission conform to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices as shown in Section 16 – Software.

2. Electrical Safety and Electromagnetic Compatibility

The Uritek TC-201 Urine Analyzer device complies with the applicable voluntary standards which include IEC 61010-1, IEC 61010-2-101, IEC 61326-1 and IEC 61326-2-6 for Electromagnetic Compatibility and Safety. The Electrical Safety and EMC Report are included in the Electromagnetic Compatibility and Electrical Safety Section 17 of the submission.

3. Analytical Performance

The analytical performance of Uritek TC-201 Urine Analyzer with the Teco Diagnostics Urine Reagent (URS-10) Strips was verified by Precision Study, Sensitivity Study, Linearity Study, Stability Study, Interference Study and Flex Study. The analytical testing and comparison testing are detailed in Performance Testing – Bench Section 18 of the submission. Below are the summaries of the testing results:

A. Precision Study:

i) In-house Precision Study:

Within Run Precision of Uritek TC-201 Urine Analyzer with the Teco Diagnostics Urine Reagent Strips (URS-10) was evaluated using commercially available urine control solutions at Level I (High analyte concentration), Level II (Low analyte concentration) and Level III (Negative). The package insert and certificate of analysis of these control solutions confirmed the specific target analyte concentration in each level. The repeatability of the Uritek TC-201 Urine Analyzer was evaluated by testing each level of control solution by three operators on three analyzers in replicates of 20 per run per day with three strip lots. A total of 180 strips were used for each level control solution tested (20 strips x 3 strip lots x 1 day x 3operators/analyzers = 180 tests per control).

As shown in the following tables, all analytes read 100% within the expected results +/- one color block. Please see Appendix 18.B for In-House Precision Study Data tables. The results from the Within-Run Precision study are summarized below:

Urine Control Level I

Analyte	Level	Exact Match Agreement	% Agreement (Exact Match)	+/- Color Block Agreement	% Agreement (+/- Color Block)	N
Glucose	1000 mg/dL	177/180	98.33	180/180	100	180

510(k) SUMMARY

Bilirubin	Large	177/180	98.33	180/180	100	180
Ketone	80 mg/dL	179/180	99.44	180/180	100	180
Specific Gravity	1.015	176/180	97.78	180/180	100	180
Blood	Large	180/180	100	180/180	100	180
Nitrite	Positive	180/180	100	180/180	100	180
Protein	300 mg/dL	180/180	100	180/180	100	180
Urobilinogen	8.0 EU/dL	180/180	100	180/180	100	180
Leukocyte	Large	180/180	100	180/180	100	180
pH	8.0	173/180	96.11	180/180	100	180

Urine Control Level II

Analyte	Level	Exact Match Agreement	% Agreement (Exact Match)	+/- Color Block Agreement	% Agreement (+/- Color Block)	N
Glucose	250 mg/dL	179/180	99.44	180/180	100	180
Bilirubin	Small	180/180	100	180/180	100	180
Ketone	40 mg/dL	180/180	100	180/180	100	180
Specific Gravity	1.010	178/180	98.89	180/180	100	180
Blood	Moderate	180/180	100	180/180	100	180
Nitrite	Positive	180/180	100	180/180	100	180
Protein	Trace	179/180	99.44	180/180	100	180
Urobilinogen	0.2 EU/dL	180/180	100	180/180	100	180
Leukocyte	Moderate	178/180	98.89	180/180	100	180
pH	8.0	179/180	99.44	180/180	100	180

Urine Control Level III

Analyte	Level	Exact Match Agreement	% Agreement (Exact Match)	+/- Color Block Agreement	% Agreement (+/- Color Block)	N
Glucose	Negative	180/180	100	180/180	100	180
Bilirubin	Negative	180/180	100	180/180	100	180
Ketone	Negative	180/180	100	180/180	100	180
Specific Gravity	1.010	179/180	99.44	180/180	100	180
Blood	Negative	180/180	100	180/180	100	180
Nitrite	Negative	180/180	100	180/180	100	180

510(k) SUMMARY

Protein	Negative	180/180	100	180/180	100	180
Urobilinogen	0.2 EU/dL	180/180	100	180/180	100	180
Leukocyte	Negative	180/180	100	180/180	100	180
pH	6.0	178/180	98.89	180/180	100	180

The Run to Run precision of Uritek TC-201 Urine Analyzer with the Teco Diagnostics Urine Reagent Strips (URS-10) was evaluated by testing each level of control solution (negative, low positive, and high positive) by two operators with three lots of URS-10 strips in three replicate assays per run, 2 non- consecutive runs each day for over 10 days on 2 Uritek TC-201 Urine Analyzer. Run 1 and Run 2 were separated by atleast 1 hour. A total of 120 strips were used for each level control solution tested (3 strips x 2 run x 10 days x 2 operators/analyzers/strip lots = 120 tests per control).

As shown in the following tables, all analytes read 100% within the expected results +/- one color block. Please see Appendix 18.B for In-House Precision Study Data tables. The results from the Run to Run Precision study are summarized below:

Urine Control Level I

Analyte	Level	Exact Match Agreement	% Agreement (Exact Match)	+/- Color Block Agreement	% Agreement (+/- Color Block)	N
Glucose	1000 mg/dL	120/120	100	120/120	100	120
Bilirubin	Large	119/120	99.17	120/120	100	120
Ketone	80 mg/dL	120/120	100	120/120	100	120
Specific Gravity	1.015	118/120	98.33	120/120	100	120
Blood	Large	120/120	100	120/120	100	120
Nitrite	Positive	120/120	100	120/120	100	120
Protein	300 mg/dL	120/120	100	120/120	100	120
Urobilinogen	8.0 EU/dL	120/120	100	120/120	100	120
Leukocyte	Large	120/120	100	120/120	100	120
pH	8.0	117/120	97.50	120/120	100	120

Urine Control Level II

Analyte	Level	Exact Match Agreement	% Agreement (Exact Match)	+/- Color Block Agreement	% Agreement (+/- Color Block)	N
Glucose	250 mg/dL	120/120	100	120/120	100	120

Bilirubin	Small	120/120	100	120/120	100	120
Ketone	40 mg/dL	120/120	100	120/120	100	120
Specific Gravity	1.010	117/120	97.50	120/120	100	120
Blood	Moderate	120/120	100	120/120	100	120
Nitrite	Positive	120/120	100	120/120	100	120
Protein	Trace	119/120	99.17	120/120	100	120
Urobilinogen	0.2 EU/dL	120/120	100	120/120	100	120
Leukocyte	Moderate	120/120	100	120/120	100	120
pH	8.0	119/120	99.17	120/120	100	120

Urine Control Level III

Analyte	Level	Exact Match Agreement	% Agreement (Exact Match)	+/- Color Block Agreement	% Agreement (+/- Color Block)	N
Glucose	Negative	120/120	100	120/120	100	120
Bilirubin	Negative	120/120	100	120/120	100	120
Ketone	Negative	120/120	100	120/120	100	120
Specific Gravity	1.010	120/120	100	120/120	100	120
Blood	Negative	120/120	100	120/120	100	120
Nitrite	Negative	120/120	100	120/120	100	120
Protein	Negative	120/120	100	120/120	100	120
Urobilinogen	0.2 EU/dL	120/120	100	120/120	100	120
Leukocyte	Negative	120/120	100	120/120	100	120
pH	6.0	120/120	100	120/120	100	120

ii) Point-of-Care Precision Study:

The precision of Uritek TC-201 Urine Analyzer at point-of-care (POC) sites was evaluated using commercially available urine control solutions at Level I (High analyte concentration), Level II (Low analyte concentration) and Level III (Negative). The package insert and certificate of analysis of these control solutions confirmed the specific target analyte concentration in each level. The three level control solutions were dispensed in to different containers and were randomly labeled with numbers. Each sample was tested in duplicates per run, two runs per day for 10 days (N = 40 testing per sample).

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510(k) SUMMARY

POC sites

Site 1: Clinica Medica Del Sagrado Corazon
831 S. Harbor Blvd. Anaheim, CA 92805
Doctor: Rouben Calatian MD

Site 2: Clinica Medica San Miquel
1306 W. Santa Ana Blvd., Santa Ana, CA 92703
Doctor: Martin Bande MD

Site 3: Artritis & Osteoporosis Center
2601 Cornerstone Blvd, Edinburg, TX 78539
Doctor: Jorge C Zamora-Quezada MD

Precision procedures provided to each POC site
Please see Appendix 18.A Precision Study Protocol for POC Sites for the detail.

Results for Point-of-Care Precision:
As shown in the following tables, all analytes read 100% within the expected results +/- one color block. Please see Appendix 18.C for Point-of-Care Run to Run Precision Data tables.

Analyte Levels Tested:

Analyte	**Target Concentration**		
	Level I	**Level II**	**Level III**
Glucose	1000 mg/dL	250 mg/dL	Negative
Bilirubin	Large	Small	Negative
Ketone	80 mg/dL	40 mg/dL	Negative
Specific Gravity	1.015	1.010	1.010
Blood	Large	Moderate	Negative
Nitrite	Positive	Positive	Negative
Protein	300 mg/dL	Trace	Negative
Urobilinogen	8.0 EU/dL	0.2 EU/dL	0.2 EU/dL
Leukocyte	Large	Moderate	Negative
pH	8.0	8.0	6.0

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510(k) SUMMARY

Results Summary:

Three POC sites combined:

	Control Level I		Control Level II		Control Level III	
Analyte	**Exact Match**	**Match within ±1 color block**	**Exact Match**	**Match within ±1 color block**	**Exact Match**	**Match within ±1 color block**
Glucose	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Bilirubin	100% (120/120)	100% (120/120)	99.17% (119/120)	100% (120/120)	100% (120/120)	100% (120/120)
Ketone	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Specific Gravity	99.17% (119/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Blood	100% (120/120)	100% (120/120)	99.17% (119/120)	100% (120/120)	100% (120/120)	100% (120/120)
Nitrite	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Protein	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Urobilinogen	99.17% (119/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Leukocyte	100% (120/120)	100% (120/120)	99.17% (119/120)	100% (120/120)	100% (120/120)	100% (120/120)
pH	98.33% (118/120)	100% (120/120)	98.33% (118/120)	100% (120/120)	100% (120/120)	100% (120/120)

B. Linearity/Assay Reportable Range

A study to evaluate the reportable range for each analyte color block on the Teco Diagnostics Urine Reagent Strips (URS-10) was performed by measuring negative urine and negative urine spiked with known increasing and decreasing concentrations of analytes relative to each color block covering the entire measuring range of each analyte present on the URS-10 strip. Sample measurement was performed in replicates of 8 by 3 operators on each of 3 individual strip lots (8 strips x 3 operators/ strip lots), for a total of 24 measurements for every sample tested. A pH meter was used to confirm the pH results. The specific gravity values were confirmed by a

510(k) SUMMARY

clinical, handheld refractometer. Specific gravity measurements were performed in replicates of 8 by 3 operators on each of 3 individual strip lots (8 strips x 3 operators/ strip lots), for a total of 24 measurements for every sample tested.
The measuring range for each concentration color block is listed in the following table based on the results of Detection Limit Study in section 18.3. Please refer to Appendix 18.F for data tables.

Table: Measuring Range of Each Color Block of URS-10 Strips

Analyte	Color Block Output Units	Measuring Range
Glucose	Negative	0.0 – 75 mg/dL
	100 mg/dL	75 – 212.5 mg/dL
	250 mg/dL	212.5 – 437.5 mg/dL
	500 mg/dL	437.5 – 875 mg/dL
	1000 mg/dL	> 875 mg/dL
Bilirubin	Negative	0.0 – 0.5 mg/dL
	Small	0.5 – 1.5 mg/dL
	Moderate	1.75 – 3.0 mg/dL
	Large	> 3.0 mg/dL
Ketone	Negative	0.0 – 3.75 mg/dL
	Trace	3.75 – 10.0 mg/dL
	15 mg/dL	10.0 – 27.5 mg/dL
	40 mg/dL	27.5 – 60.0 mg/dL
	80 mg/dL	> 60.0 mg/dL
Blood	Negative	0 – 7.5 Ery/µL
	Trace	7.5 – 21.25 Ery/µL
	Small	21.25 – 52.5 Ery/µL
	Moderate	52.5 – 170 Ery/µL
	Large	> 170 Ery/µL
Protein	Negative	0.0 – 11.25 mg/dL
	Trace	11.25 – 26.25 mg/dL
	30 mg/dL	26.25 – 65 mg/dL
	100 mg/dL	65 – 200 mg/dL
	300 mg/dL	> 200 mg/dL
Nitrite	Negative	0.0 – 0.075 mg/dL
	Positive	> 0.075 mg/dL
Leukocyte	Negative	0.0 – 11.25 ca cells/µL
	Trace	11.25 – 56.25 ca cells/µL
	Small	56.25 – 111.25 ca cells/µL
	Moderate	111.25 – 406.25 ca cells/µL

	Large	> 406.25 ca cells/µL
Urobilinogen	0.2 mg/dL	0.2 – 0.6 mg/dL
	1.0 mg/dL	0.6 – 1.5 mg/dL
	2.0 mg/dL	1.5 – 3.0 mg/dL
	4.0 mg/dL	3.0 – 6.0 mg/dL
	8.0 mg/dL	> 6.0 mg/dL
pH	5.0	5.0
	6.0	6.0
	6.5	6.5
	7.0	7.0
	7.5	7.5
	8.0	8.0
	8.5	8.5
SG	1.005	1.005
	1.010	1.010
	1.015	1.015
	1.020	1.020
	1.025	1.025
	1.030	1.030

C. Traceability and Stability:

Traceability and Expected Value:
Three levels of commercial urine controls that represent values as negative, low and high for all 10 URS parameters were used to assess the quality, the integrity and the stability of URS-10 strips during the manufacturing process and the storage of the strips. The package insert and certificate of analysis of these control solutions confirmed the specific target analyte concentration in each level. These controls were purchased from a commercially available supplier (HYCOR Biomedical), who sells their controls for standard testing throughout the world.

The expected ranges for all controls used for testing URS-10 strips are listed in the following table. Please see Appendix 18.D for the control details.

Table I: Urine Control Acceptable Range

Analyte	**Level I**	**Level II**	**Level III**
Glucose	500 – ≥ 1000 mg/dL	100 – 500 mg/dL	Negative
Bilirubin	Moderate to Large	Small to Moderate	Negative

510(k) SUMMARY

Ketone	40 – ≥ 80 mg/dL	Trace – 40 mg/dL	Negative
Specific Gravity	1.010 – 1.030	≤ 1.005 - 1.020	≤ 1.005 - 1.015
Blood	Moderate to Large	Trace to Moderate	Negative
Nitrite	Positive	Positive	Negative
Protein	100 – ≥ 300 mg/dL	Negative to 30 mg/dL	Negative
Urobilinogen	4.0 – ≥ 8.0 EU/dL	0.2 – 1.0 EU/dL	0.2 - 1.0 EU/dL
Leukocyte	Small to Large	Trace to Moderate	Negative
pH	7.0 – 8.5	7.0 - 8.5	5.0 - 7.0

Stability:
Although the Teco Diagnostics URS-10 strips (K970250) have already passed all the Stability studies and approved by FDA for commercial use but we are performing three types of stability studies to assess the stability of URS-10 reagent strips with our new Uritek TC-201 urine analyzer.

(1) Open bottle study:
To monitor URS-10 strip's integrity after the strip bottle has been opened for use, open bottle study was conducted. This study involves testing URS-10 strips once per week periodically on TC-201 device, for 13 weeks using commercial urine controls levels I, II and III. Three (3) lots of URS-10 strip bottles used in the Open-vial Study will have passed Quality Control inspection and are opened (seals broken) and stored at room temperature (15-30°C) and 20-30% humidity.
The acceptance criteria was that the tested strips must read all controls within the expected ranges as listed in the package insert for ≥ 90 days (pass 13 weeks) to confirm the statement "Do not use after 90 days of breaking the foil" on the URS-10 strip bottle label.

(2) Accelerated stability study:
Besides being used for testing product's integrity, accelerated stability study is often carried out to assess the shelf-life of a new product, which is verified in real-time studies. Accelerated stability study involves testing URS-10 strips once per week periodically on TC-201 device, for 13 weeks using commercial urine controls levels I, II and III. Three (3) lots of URS-10 strip bottles used in the Accelerated stability study will have passed Quality Control inspection and are sealed and stored at 37°C ± 2°C oven and 20-30% humidity. The acceptance criteria was that the tested strips must read all controls within the expected ranges as listed in Table 18.3.1 for ≥ 90 days (pass 13 weeks) to confirm the sealed URS-10 strips bottle shelf life of two (2) years at room temperature (15-30°C) with 20-30% humidity.

(3) Real-time shelf-life study:
A real time, temperature and humidity stability study is currently being performed on sealed bottles of URS-10 strips to validate the claims stated in the Accelerated Stability Studies. This

510(k) SUMMARY

study involves testing the URS-10 strips on TC-201 device using commercial urine control levels I, II and III for every six (6) months from the manufactured date, until 18 months. After the URS-10 strips has passed 18 months, test every three (3) months until the product fails or until 27 months (3 months after the stated expiration date). Three (3) lots of URS-10 strips used in the Real Time Shelf Life Study will have passed Quality Control inspection and are sealed and stored at room temperature (15-30°C) and 20-30% humidity. The current strip label has an expiration date of 2 years.
The acceptance criteria was that the tested strips must read all controls within the expected ranges as listed in the package insert in real-time through its expiration date in the conditions that the product will be stored: sealed bottle, room temperature (15-30°C)

Results of all the stability studies are summarized in the following table. Please see Appendix 18.E Stability Study Data for data table.

Table: Stability Study Test Results

URS-10 Strip Lot no.	Urine Control Level	Stability Study		
		Open Bottle	Accelerated stability	Real time Shelf Life
63726	Level I	Pass	Pass	Ongoing study
	Level II	Pass	Pass	Ongoing study
	Level III	Pass	Pass	Ongoing study
63886	Level I	Pass	Pass	Ongoing study
	Level II	Pass	Pass	Ongoing study
	Level III	Pass	Pass	Ongoing study
64020	Level I	Pass	Pass	Ongoing study
	Level II	Pass	Pass	Ongoing study
	Level III	Pass	Pass	Ongoing study

D. Detection Limit

Sensitivity Study was performed to determine the cutoff point concentration at which each analyte on the URS-10 strip changed from negative to the positive color blocks. Samples were prepared by spiking the specified analyte concentration into negative urine with a minimum of 4 levels across the measuring range for each color block. Each pool was then analyzed in replicates of 8 by 3 operators on each of the 3 individual strip lots (8 strips x 3 operators/ strip lots), for a total of 24 data points for each level. The cutoff point determination study for each color block for each analyte is defined as the lowest concentration at which >55% of the test results are positive.

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510(k) SUMMARY

The cut-off values and percentage sensitivity for each color block for individual analyte is summarized and demonstrated in the table below:

Analyte	Color Block	Cut-off	% Positive Results
Glucose	100 mg/dL	75 mg/dL	67%
	250 mg/dL	212.5 mg/dL	83%
	500 mg/dL	437.5 mg/dL	83%
	1000 mg/dL	875 mg/dL	75%
Bilirubin	Small	0.5 mg/dL	59%
	Moderate	1.75 mg/dL	87.5%
	Large	3.0 mg/dL	62.5%
Ketone	Trace	3.75 mg/dL	71%
	15 mg/dL	10 mg/dL	71%
	40 mg/dL	27.5 mg/dL	91%
	80 mg/dL	60 mg/dL	75%
Blood	Trace	7.5 Ery/µL	71%
	Small	21.25 Ery/µL	75%
	Moderate	52.5 Ery/µL	67%
	Large	170 Ery/µL	71%
Protein	Trace	11.25 mg/dL	91%
	30 mg/dL	26.25 mg/dL	75%
	100 mg/dL	65 mg/dL	87%
	300 mg/dL	200 mg/dL	87%
Nitrite	Positive	0.075 mg/dL	58%
Leukocyte	Trace	11.25 ca cells/µL	58%
	Small	56.25 ca cells/µL	67%
	Moderate	111.25 ca cells/µL	58%
	Large	312.5 ca cells/µL	67%
Urobilinogen	0.2 mg/dL	0.2 mg/dL	100%
	1.0 mg/dL	0.8 mg/dL	71%
	2.0 mg/dL	2.0 mg/dL	90%
	4.0 mg/dL	3.5 mg/dL	55%
	8.0 mg/dL	7.0 mg/dL	85%
pH	5.0	5.0	96%
	6.0	6.0	100%
	6.5	6.5	96%
	7.0	7.0	96%
	7.5	7.5	96%
	8.0	8.0	96%
	8.5	8.5	96%

SG	1.005	1.005	92%
	1.010	1.010	92%
	1.015	1.015	92%
	1.020	1.020	92%
	1.025	1.025	92%
	1.030	1.030	92%

E. Analytical Specificity

Endogenous and Exogenous Interference Study:
Potential endogenous interferents and drugs commonly found in urine were evaluated to assess the interfering effect of various substances on the performance of URS-10 strips on Uritek TC-201 Urine Analyzer. At least 2 levels of the listed interferents were added to the urine sample pools which were prepared at 3 concentrations for each urine chemistry analyte; negative, low positive and high positive. Each urine sample was tested with 3 replicates using Uritek TC-201 Urine Analyzer. Interference was defined as a change in output of ± 1 color blocks between spiked and unspiked control sample for all the URS parameters.
The concentrations of the potential interfering substances that did not have any influence on the test results are listed below:

Potential Interfering Substance	Highest Concentration of substance tested which demonstrated no Interference
Ascorbic Acid	30 mg/dL
Ammonium Chloride	200 mg/dL
Albumin	≤125 mg/dL
Bilirubin	8 mg/dL
Creatine	10 mg/dL
Lithium Acetoacetate	≤60 mg/dL
Calcium Chloride	100 mg/dL
Citric Acid	50 mg/dL
Creatinine	200 mg/dL
D (+) Glucose	1500 mg/dL
Glycine	450 mg/dL
Hemoglobin	10 mg/dL
Potassium Chloride	1500 mg/dL
Sodium Chloride	4000 mg/dL
Oxalic Acid	35 mg/dL
Sodium Acetate	25 mg/dL
Sodium Nitrate	10 mg/dL

510(k) SUMMARY

Sodium Nitrite	10 mg/dL
Sodium Phosphate	500 mg/dL
Uric Acid	150 mg/dL
Urea	4000 mg/dL
Riboflavin	10 mg/L
Theophylline	100 mg/L
D (+) Galactose	80 mg/dL
Fructose	100 mg/dL
Lactose	10 mg/dL
Leucocytes	3000 cells/µL
Blood	≤0.01%
Human Immunoglobulins	25 mg/dL
Formalin	92.5 mg/dL
Amoxicillin	30 mg/dL
Nitrofurantoin	60 mg/dL
Gentamicin sulfate	6 mg/dL
Acetaminophen	40 mg/dL

The following table shows the substances which did interfere with one or more of the Teco Diagnostics URS-10 analytes. Results are expressed as the lowest concentration of interfering substance that exhibited interference and the resulting change in output of color block.

Analyte	Concentration of Substance at which Interference was observed	Change in Color block Output
Glucose	Blood (≥ 5%), Hypochlorite (≥ 0.6%), Pyridium (≥ 50 mg/dL)	+1,
	Ascorbic Acid (≥ 75 mg/dL), Amoxicillin (≥ 100 mg/dL), Acetylcysteine (≥ 135 mg/dL)	-1
Protein	Hemoglobin (≥ 20 mg/dL), Blood (≥ 1%), Sodium Bicarbonate (1500 mg/dL), Chloroquine (≥ 20 mg/dL), Pyridium (≥ 50 mg/dL), pH (> 8.5)	+1, +2 to +3, +1 to +2, +1
	Amoxicillin (≥ 100 mg/dL), Hypochlorite (≥ 0.6%), SG (> 1.030)	-1
Bilirubin	Blood (≥ 5%), Pyridium (≥ 50 mg/dL)	+2 to +3
	Formalin (≥ 185 mg/dL), Boric Acid (≥ 500 mg/dL), Acetylcysteine (≥ 67.5 mg/dL), Hypochlorite (≥ 0.6%)	-1
Urobilinogen	Blood (≥ 1%)	+1
	Hypochlorite (≥ 0.6%)	-2
SG	Albumin (≥ 200 mg/dL), Blood (≥ 1%)	+1

	Nitrofurantoin (≥ 120 mg/dL)	-1 to -2
pH	SG (> 1.030), Sodium Bicarbonate (≥ 750 mg/dL), Sodium Phosphate (≥ 250 mg/dL), Creatinine (≥ 400 mg/dL)	+1 to +2
	Ascorbic Acid (≥75 mg/dL), Calcium Chloride (≥ 275 mg/dL) Citric Acid (≥ 75 mg/dL), Sodium Chloride (≥ 6000 mg/dL), Oxalic Acid (≥ 70 mg/dL)	-1 to -2
Blood	Albumin (200 mg/dL), Hypochlorite (≥ 0.6%)	+2
	Acetylcysteine (≥ 67.5 mg/dL)	-1
Nitrite	Blood (≥ 1%), Hypochlorite (≥ 0.6%), Pyridium (≥ 50 mg/dL)	+1
Leukocytes	Blood (≥ 1%), Pyridium (≥ 50 mg/dL)	+1 to +2,
	Glucose (≥ 2000 mg/dL), Boric Acid (≥ 500 mg/dL), Chloroquine (≥ 20 mg/dL), Amoxicillin (≥ 100 mg/dL), Hypochlorite (≥ 0.6%)	-1, -1 to -2
Ketone	Blood (≥ 5%), Acetylcysteine (≥ 67.5 mg/dL), Pyridium (≥ 50 mg/dL)	+1, +2 to +3
	Hypochlorite (≥ 0.6%)	-1 to -2

pH Interference Study:
The sponsor performed an additional study to evaluate the effect of sample pH on the test results for the ten analytes in human urine. The study result shows that sample pH from 5.0 to 9.0 does not affect the test results for leukocytes, urobilinogen, ketone, pH, blood, nitrite, bilirubin and glucose. Samples with pH greater than 8.5 affected the protein test resulting in a false high result.

Specific Gravity Interference Study:
The sponsor performed an additional study to evaluate the effect of sample specific gravity on the test results for the ten analytes in human urine. The study result shows that sample specific gravity from 1.000 to 1.040 does not affect the test results for leukocytes, urobilinogen, ketone, blood, nitrite, bilirubin and glucose. Samples with specific gravity greater than 1.030 affected the pH and protein tests resulting in a false low result.
Based on the results of this testing the sponsor has included the effects from above interfering substances in the labeling as limitations of procedure.

F. Flex Study
Temperature and Humidity Study:
The environmental effect on the performance of Uritek TC-201 Urine Analyzer and URS-10 strips was evaluated by placing the strips in relative humidity of <20%, 30%, 50%, 60% and 70% environment at 15°C and 45°C. Strips were removed at 0.5h, 1h, 2h, 4h, 8h, 16h and 24h for testing using commercially available urine control solutions at Level I (High analyte concentration), Level II (Low analyte concentration) and Level III (Negative).

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510(k) SUMMARY

Teco Diagnostics URS-10 strips were stable up to 70% humidity for over 24h at either 15°C or 45°C. 3 replicates of strips tested passed each control level at 100% exact match. Please see Appendix 18.H Humidity Study Data for data tables.

Timing Flex Study:

The effect of various dipping time in urine samples was evaluated for the performance of the Teco Diagnostics URS-10 strip. The strip was dipped in the urine samples for 1 second, 5 seconds and 10 seconds before removed for testing using commercially available urine control solutions at Level I (High analyte concentration), Level II (Low analyte concentration) and Level III (Negative). Results showed that the dipping time had no interfering effect on the test. Please see Appendix 18.I Timing Flex Study Data for data tables.

Sample Running Over Study:

The interference of samples running over from one pad to the adjacent pad on the performance of URS-10 strip was evaluated. The strip was dipped into a urine sample and upon removal, was held upward to allow the sample flow from the leukocyte pad to the next aligned pads or held downward to allow the sample flow from the glucose pad to the next aligned pads before testing. Commercially available urine control solutions at Level I (High analyte concentration), Level II (Low analyte concentration) and Level III (Negative) were used for testing. Results demonstrate that sample running over from one test pad had no interfering effect on the test of the other pad. Please see Appendix 18.J Sample Running Over Study Data for data tables.

Analyzer Operating Conditions Study:

All the performance testing (linearity, sensitivity and interference) was carried out at ideal laboratory conditions 15-20°C and 15-30% Relative Humidity.

An additional study was performed to ensure the claim of acceptable operating conditions at 15-30°C and 18-80% Relative Humidity for the Uritek TC-201 Urine Analyzer. The performance of Uritek TC-201 Urine Analyzer and URS-10 strips was evaluated by placing the Uritek TC-201 Urine analyzer in relative humidity of >80% environment at ≥30°C. These conditions were manufactured artificially in the Laminar Air Flow Cabinet by placing Hot Water Steam Bath and a Humidifier. Tests were performed at particular time-points at 0.1h, 8h, 16h and 24h using commercially available urine control solutions at Level I (High analyte concentration), Level II (Low analyte concentration) and Level III (Negative).

Uritek TC-201 Urine Analyzer was stable at 92% humidity for over 24h at 30°C. The acceptance criteria was that the tested strips must read all controls within the expected ranges as listed in Table 18.3.1. 5 replicates of strips tested passed for each control level. Please see Appendix 18.M Analyzer Operating Conditions Study Data for data tables.

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510(k) SUMMARY

4. Comparison Study

A. Method Comparison with Predicate Device:

Three Point-of-Care (POC) Sites that represented the intended user sites of these devices were selected to perform the method comparison studies to evaluate the performance of the Teco Diagnostics Urinalysis Reagent Strip (URS-10) read by the Uritek TC-201 Urine Analyzer compared to the performance of the predicate method, Siemens Multistix 10 SG Reagent strip read by Siemens Clinitek Status+ Urine Analyzer. Each site randomly selected at least 115, unaltered patient samples to test on both device pairings. In order to evaluate the performance of the candidate device over the entire measuring range of each analyte, additional contrived samples (10% of the total samples) were tested resulting in up to 392 specimens evaluated at all sites. Three lots of Teco Diagnostics Urinalysis Reagent Strip (URS-10) and 3 units of Uritek TC-201 Urine Analyzer were used in the study (detailed information is provided in Appendix 18.L). Three operators at each site ran the samples.
An additional method comparison study was performed at POC Site I and Site II for a total of 91 clinical samples to demonstrate the substantial equivalence accuracy for all the URS parameters. Moreover a separate study was performed at Site I wherein the patient urine samples were prescreened at pH ≥ 8.0 using a standardized pH meter and then performed the method comparison study using Uritek TC-201 Urine Analyzer and Siemens Clinitek Status+ Urine Analyzer. The total number of patient urine specimens evaluated in the Method Comparison Study is 509. (392+91+26)
Gender and unique patient identifiers were recorded for each sample tested. Testing results are summarized in the following tables.

Glucose		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		1000	500	250	100	Neg	Overall
Uritek TC-201 Urine Analyzer	1000	16	4	0	0	0	20
	500	4	37	0	0	0	41
	250	0	0	10	0	0	10
	100	0	0	0	25	0	25
	Neg	0	0	0	0	413	413
	Total	20	41	10	25	413	509
Agreement within same color block (Exact Match)		80.00% (16/20)	90.24% (37/41)	100.0% (10/10)	100.0% (25/25)	100.0% (413/413)	98.43% (501/509)
Agreement within ±1 color block		100.0% (20/20)	100.0% (37/41)	100.0% (10/10)	100.0% (25/25)	100.0% (413/413)	100.0% (509/509)

Glucose concentration levels compared at a 98.43% overall exact match and a 100.0% overall agreement ±1 color block match between the Uritek TC-201 Urine Analyzer and Siemens Clinitek Status+ Analyzer.

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510(k) SUMMARY

Bilirubin		Siemens Clinitek Status + Urine Analyzer				
3 Sites, N=509		3+	2+	1+	Neg	Overall
Uritek TC-201 Urine Analyzer	3+	35	1	0	0	36
	2+	0	31	0	0	31
	1+	0	0	51	5	56
	Neg	0	0	0	386	386
	Total	35	32	51	391	509
Agreement within same color block (Exact Match)		100.0% (35/35)	96.88% (31/32)	100.0% (51/51)	98.72% (386/391)	98.82% (503/509)
Agreement within ±1 color block		100.0% (35/35)	100.0% (32/32)	100.0% (51/51)	100.0% (391/391)	100.0% (509/509)

Bilirubin concentration levels compared at a 98.82% overall exact match and a 100.0% overall agreement ±1 color block match between the Uritek TC-201 Urine Analyzer and Siemens Clinitek Status+ Analyzer.

Ketone		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		80	40	15	Trace	Neg	Overall
Uritek TC-201 Urine Analyzer	80	13	1	0	0	0	14
	40	0	18	1	0	0	19
	15	0	0	24	1	0	25
	TRA	0	0	0	44	4	48
	Neg	0	0	0	1	402	403
	Total	13	19	25	46	406	509
Agreement within same color block (Exact Match)		100.0% (13/13)	94.74% (18/19)	96.0% (24/25)	95.65% (44/46)	99.01% (402/406)	98.43% (501/509)
Agreement within ±1 color block		100.0% (13/13)	100.0% (19/19)	100.0% (25/25)	100.0% (46/46)	100.0% (406/406)	100.0% (509/509)

Ketone concentration levels compared at a 98.43% overall exact match and a 100.0% overall agreement ±1 color block match between the Uritek TC-201 Urine Analyzer and Siemens Clinitek Status+ Analyzer.

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510(k) SUMMARY

Specific Gravity		Siemens Clinitek Status + Urine Analyzer						
3 Sites, N=509		≥1.030	1.025	1.020	1.015	1.010	≤1.005	Overall
Uritek TC-201 Urine Analyzer	>1.030	57	5	0	0	0	0	62
	1.025	6	55	5	0	0	0	66
	1.020	0	21	112	10	0	0	143
	1.015	0	0	16	135	6	0	157
	1.010	0	0	0	8	40	7	55
	<1.005	0	0	0	0	4	22	26
	Total	63	81	133	153	50	29	509
Agreement within same color block (Exact Match)		90.48% (57/63)	67.90% (55/81)	84.21% (112/133)	88.24% (135/153)	80.0% (40/50)	75.86% (22/29)	82.71% (421/509)
Agreement within ±1 color block		100.0% (63/63)	100.0% (81/81)	100.0% (133/133)	100.0% (153/153)	100.0% (50/50)	100.0% (29/29)	100.0% (509/509)

Specific Gravity concentration levels compared at a 82.71% overall exact match and a 100.0% overall agreement ±1 color block match between the Uritek TC-201 Urine Analyzer and Siemens Clinitek Status+ Analyzer.
*The Acceptance Criteria for SG is +/- 0.005.

Blood		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		3+	2+	1+	Trace	Neg	Overall
Uritek TC-201 Urine Analyzer	3+	32	3	0	0	0	35
	2+	0	55	0	0	0	55
	1+	0	0	21	0	0	21
	Trace	0	0	1	63	2	66
	Neg	0	0	0	4	328	332
	Total	32	58	22	67	330	509
Agreement within same color block (Exact Match)		100.0% (32/32)	94.83% (55/58)	95.45% (21/22)	94.03% (63/67)	99.39% (328/330)	98.04% (499/509)
Agreement within ±1 color block		100.0% (32/32)	100.0% (58/58)	100.0% (22/22)	100.0% (67/67)	100.0% (330/330)	100.0% (509/509)

Blood concentration levels compared at a 98.04% overall exact match and a 100.0% overall agreement ±1 color block match between the Uritek TC-201 Urine Analyzer and Siemens Clinitek Status+ Analyzer.

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510(k) SUMMARY

Protein		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		>300	100	30	Trace	Neg	Overall
Uritek TC-201 Urine Analyzer	>300	26	0	0	0	0	26
	100	0	35	0	0	0	35
	30	0	3	34	0	0	37
	Trace	0	0	2	46	6	54
	Neg	0	0	0	3	354	357
	Total	26	38	36	49	360	509
Agreement within same color block (Exact Match)		100.0% (26/26)	92.11% (35/38)	94.44% (34/36)	93.88% (46/49)	98.33% (354/360)	97.25% (495/509)
Agreement within ±1 color block		100.0% (26/26)	100.0% (38/38)	100.0% (36/36)	100.0% (49/49)	100.0% (360/360)	100.0% (509/509)

Protein concentration levels compared at a 97.25% overall exact match and a 100.0% overall agreement ±1 color block match between the Uritek TC-201 Urine Analyzer and Siemens Clinitek Status+ Analyzer.

Urobilinogen		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		>8.0	4	2	1	0.2	Overall
Uritek TC-201 Urine Analyzer	>8.0	31	0	0	0	0	31
	4.0	0	26	0	0	0	26
	2.0	0	0	22	0	0	22
	1.0	0	0	0	14	0	14
	0.2	0	0	0	2	414	416
	Total	31	26	22	16	414	509
Agreement within same color block (Exact Match)		100.0% (31/31)	100.0% (26/26)	100.0% (22/22)	87.5% (14/16)	100.0% (414/414)	99.61% (507/509)
Agreement within ±1 color block		100.0% (31/31)	100.0% (26/26)	100.0% (22/22)	100.0% (16/16)	100.0% (414/414)	100.0% (509/509)

Urobilinogen concentration levels compared at a 99.61% overall exact match and a 100.0% overall agreement ±1 color block match between the Uritek TC-201 Urine Analyzer and Siemens Clinitek Status+ Analyzer.

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510(k) SUMMARY

pH		Siemens Clinitek Status + Urine Analyzer							
3 Sites, N=509		8.5	8	7.5	7.0	6.5	6.0	5.0	Overall
Uritek TC-201 Urine Analyzer	8.5	36	0	0	0	0	0	0	36
	8.0	2	15	5	0	0	0	0	22
	7.5	1	1	34	1	0	0	0	37
	7.0	0	0	0	100	0	0	0	100
	6.5	0	0	0	8	65	1	0	74
	6.0	0	0	0	0	11	89	8	108
	5.0	0	0	0	0	1	9	122	132
	Total	39	16	39	109	77	99	130	509
Agreement within same color block (Exact Match)		92.31% (36/39)	93.75% (15/16)	87.18% (34/39)	91.74% (100/109)	84.42% (65/77)	89.90% (89/99)	93.85% (122/130)	90.57% (461/509)
Agreement within ±1 color block		97.44% (38/39)	100.0% (16/16)	100.0% (39/39)	100.0% (109/109)	98.70% (76/77)	100.0% (99/99)	100.0% (130/130)	99.61% (507/509)

pH concentration levels compared at an 90.57% overall exact match and a 99.61% overall agreement ±1 color block match between the Uritek TC-201 Urine Analyzer and Siemens Clinitek Status+ Analyzer.

Nitrite		Siemens Clinitek Status + Urine Analyzer		
3 Sites, N=509		POS	NEG	Overall
Uritek TC-201 Urine Analyzer	POS	80	2	82
	NEG	1	426	427
	Total	81	428	509
Agreement within same color block (Exact Match)		98.77% (80/81)	99.53% (426/428)	99.41% (506/509)
Agreement within ±1 color block		N/A	N/A	N/A

Nitrite concentration levels compared at a 99.41% overall exact match between the Uritek TC-201 Urine Analyzer and Siemens Clinitek Status+ Analyzer.

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510(k) SUMMARY

Leukocyte		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		3+	2+	1+	Trace	Neg	Overall
Uritek TC-201 Urine Analyzer	3+	39	0	0	0	0	39
	2+	0	12	0	0	0	12
	1+	0	1	49	0	0	50
	Trace	0	0	1	27	7	35
	Neg	0	0	0	2	371	373
	Total	39	13	50	29	378	509
Agreement within same color block (Exact Match)		100.0% (39/39)	92.31% (12/13)	98.00% (49/50)	93.10% (27/29)	98.15% (371/378)	97.84% (498/509)
Agreement within ±1 color block		100.0% (39/39)	100.0% (12/13)	100.0% (50/50)	100.0% (29/29)	100.0% (378/378)	100.0% (509/509)

Leukocyte concentration levels compared at a 97.84% overall exact match and a 100% overall agreement ±1 color block match between the Uritek TC-201 Urine Analyzer and Siemens Clinitek Status+ Analyzer.

B. Matrix Comparison:
Not applicable.

5. Clinical Study:
Not applicable.

6. Expected Values/Reference Range:

Glucose: Small amounts of glucose are normally excreted by the kidney.[5] Concentrations as little as 0.1 g/dl glucose, read either at 10 or 30 seconds, may be significantly abnormal if found consistently. At 10 seconds, results should be interpreted qualitatively; for semi-quantitative results, read at 30 seconds only.

Bilirubin: Normally, no bilirubin is detectable in urine by even the most sensitive method. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Atypical colors (colors produced which are different than the negative or positive color blocks shown on the Color Chart) may indicate that bilirubin derived bile pigments are present in the urine sample and are possibly masking the bilirubin reaction.

510(k) SUMMARY

Ketone: Normally, no ketones are present in urine. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise.[6-8] In starvation diets, or in other abnormal carbohydrate metabolism situation, ketones appear in the urine in excessively large amounts before serum ketones are elevated.[9]

Specific Gravity: Random urine may vary in specific gravity from 1.003-1.040+. Twenty-four hour urine from normal adults with normal diets and normal fluid intake will have a specific gravity of 1.016-1.022.[10]

Blood: Any green spots or green color developing on the reagent area within 40 seconds is significant and the urine should be examined further. Blood is frequently, but not invariably found in the urine of menstruating females.

pH: The normal pH of urine can range from 4.5-8.0. The average pH values in healthy subjects is 6.0.[3]

Protein: In 24-hour urine, 1-14 mg/dl of protein may be excreted by the normal kidney.[4] A color matching any color block greater than trace indicates significant proteinuria. For urine with high specific gravity, the test area may most closely match the trace color block even though only normal concentrations of protein are present. Clinical judgment is needed to evaluate the significance of trace results.

Urobilinogen: In a healthy population, the normal urine urobilinogen range obtained with this test is 0.2-1.0 Ehrlich Unit/dL. A result of 2.0 EU/dL may be of clinical significance and the same patient sample should be evaluated further.

Nitrite: Normally no detectable amount of nitrite is present in urine.[3] The nitrite area will be positive in a proportion of cases of significant infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test range from as low as 40%, in instances where little bladder incubation occurred, to as high as 80% in instances where a minimum of 4 hours incubation occurred.

Leukocytes: Normal urine specimens generally yield negative results with this test. A trace result may be of questionable clinical significance and it is recommended that the test be repeated using a fresh sample from the same patient. Repeated trace and positive results are of clinical significance.

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510(k) SUMMARY

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510(k) SUMMARY

IX. Conclusion:

Device verification and validation testing confirms that product specifications are met, which supports the intended use and technological characteristic as the predicate devices. The information provided supports the substantial equivalence to the predicate device and that the system is safe and effective for the users/operators.

The performance characteristics of the Uritek TC-201 Urine Analyzer with the Urine Reagent (URS-10) Strips were verified by were verified by precision study, linearity study, traceability study, stability study, detection limit study, specificity study, and flex study. Testing results indicate that the Uritek TC-201 Urine Analyzer and Urine Reagent (URS-10) Strips perform satisfactorily when used appropriately, as outlined in the package insert.

Method comparison study results demonstrate a substantial equivalency on performance between Uritek TC-201 with Urine Reagent (URS-10) Strips and the predicate device, Clinitek Status Plus Urine Analyzer with Clinitek Multistix 10 SG Strips. In summary, the results present here support the substantial equivalence to the predicate device.