



Food and Drug Administration
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TECO DIAGNOSTICS, INC.
YUNYUAN VIVIAN WANG
R&D MANAGER
1268 N. LAKEVIEW AVE.
ANAHEIM CA 92807

March 7, 2016

Re: K152835

Trade/Device Name: Uritek TC-201 Urine Chemistry Test System
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: JFY, JIR and KQO
Dated: January 27, 2016
Received: January 28, 2016

Dear Dr. Yunyuan Vivian Wang:

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 [SELECT ONE: Part 801 [or, for IVDs only] 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 regulation (21 CFR Part 801), 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" (21CFR 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

Indications for Use

510(k) Number (if known)

K152835

Device Name

Uritek TC-201 Urine Chemistry Test System

Indications for Use (Describe)

Uritek TC-201 Urine Chemistry Test System consists of Uritek TC-201 Urine Analyzer and Urine Microalbumin Creatinine Strips. The Uritek TC-201 Urine Analyzer is an automated, bench top instrument which is intended for prescription, in vitro diagnostic use only. It is intended for use only at Point-of-Care (POC) sites by professionals. The device is intended to be used together with the Urine Microalbumin Creatinine (UAC) Strips as a system for the semi-quantitative detection of Microalbumin and Creatinine and determination of the albumin to creatinine ratio in urine. Test results may be used in screening urine specimens for microalbuminuria as an aid in the detection of patients at risk for developing kidney damage.

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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Section 5 -- 510(k) SUMMARY**I. SUBMMITER****Applicant Information:**

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

Contact Person: Yunyuan Vivian Wang, Ph. D.
R&D Manager
Email: vwang@tecodiag.com

Date Prepared: September 28th, 2015

II. DEVICE**Device Name:**

Uritek TC-201 Urine Chemistry Test System

Common Name:

Automated Urinalysis System, Urinary Test System

Regulatory Information:

1. Regulation Classification section:
 - Class II: 21 CFR 862.1225 – Creatinine test system
 - Class I: 21 CFR 862.1645 – Urinary protein or albumin (nonquantitative) test system
 - Class I: 21 CFR 862.2900 –Automated urinalysis system (exempt).
2. Product Code:
 - JFY – Enzymatic Method, Creatinine
 - JIR – Indicator Method, Protein or Albumin (Urinary, Non-Quant.)
 - KQO – Automated urinalysis system
3. Panel:
 - Clinical Chemistry

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III. PREDICATE DEVICE

[Clinitek Status Plus Analyzer and Siemens Reagent Strips for Urinalysis](#)

SIEMMENS HEALTHCARE DIAGNOSTICS

2 Edgewater Dr.

Norwood, MA 02062

510(k) Number: k091216

IV. DEVICE DESCRIPTION

Uritek TC-201 Urine Chemistry Test System consists of Uritek TC-201 Urine Analyzer and Urine Microalbumin Creatinine Strips. The Uritek TC-201 Urine Analyzer (TC-201) is a portable easy to use instrument which reads Teco Diagnostics' Urine Microalbumin Creatinine (UAC) 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 microalbumin and creatinine. 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 user interface touch screen on the front surface of the instrument.

The Urine Microalbumin Creatinine (UAC) Strips are urine test strips of which microalbumin and creatinine 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. UAC strips provide tests for the semi-quantitative detection of Microalbumin (low concentration of Albumin) and Creatinine and determination of the Albumin to Creatinine ratio (A : C) in urine.

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V. INDICATIONS FOR USE

Uritek TC-201 Urine Chemistry Test System consists of Uritek TC-201 Urine Analyzer and Urine Microalbumin Creatinine Strips. The Uritek TC-201 Urine Analyzer is an automated, bench top instrument which is intended for prescription, in vitro diagnostic use only. It is intended for use only at Point-of-Care (POC) sites by professionals. The device is intended to be used together with the Urine Microalbumin Creatinine (UAC) Strips as a system for the semi-quantitative detection of Microalbumin and Creatinine and determination of the albumin to creatinine ratio in urine. Test results may be used in screening urine specimens for microalbuminuria as an aid in the detection of patients at risk for developing kidney damage.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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

Similarities and Differences		
	Device	Predicate
Trade Name	Uritek TC-201 Urine Chemistry Test System	Siemens Reagent Strips for Urinalysis
Intended Use	Intended for prescription, in vitro diagnostic use only.	Same
Specimen Type	Urine	Same
Device Methodology	Reflectance Photometer	Same
Analytical Method	The analyzer measures the intensity of the light reflected from the reagent pads of a urinalysis reagent strip.	Same

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Chemistry Strips	Urine Microalbumin Creatinine Strips (UAC)	Siemens Reagent Strips for Urinalysis
Testing Parameters	Microalbumin, Creatinine	Microalbumin, Creatinine, Bilirubin, Blood (Occult), Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, Specific Gravity, Urobilinogen, and human Chorionic Gonadotropin (hCG)
Micro-Albumin Methodology	Indicator method based on dye binding using a high affinity sulfonephthalein dye. At a constant pH, the development of a blue color is due to the presence of Micro-Albumin. The resulting color ranges from pale green to aqua blue.	Same
Creatinine Methodology	Indicator method based on the peroxidase-like activity of a copper creatinine complex that catalyze the reaction of diisopropylbenzene dihydroperoxide and 3', 3', 5', 5' – tetramethylbenzidine. The resulting color ranges from orange through green to blue.	Same
Detection Range	Detects albumin concentration from 10mg/L to 150mg/L Detects creatinine concentration from 10mg/dL to 300mg/dL	Same
Calculated Parameter	Albumin : Creatinine Ratio	Same
Calibration Method	Self-calibration with the white area located at the back of the test strip bed	Same
Operating interface	Touch Screen	Same
Entered Parameter	Urine Color and Clarity, Patient ID, Operator ID	Same
Printer	Built-in thermal printer	Same

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PC Port	Standard RS232 serial Port USB Port	Same
Power	Input 100-240 V \pm 20% and 45-65Hz, output + 9V	Same
Line Leakage Current	<0.5mA	Same
Analyzer Operating Conditions	18-30°C (64-86°F); 18%-80% Relative Humidity (non-condensing)	Same
Battery Powered Operation	None	6 AA non-rechargeable alkaline batteries
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)

VII. PERFORMANCE DATA
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 Pre-market 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

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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 Chemistry Test System was verified by Precision Study, Sensitivity Study, Stability Study, Interference Study, Flex Study. The testing results are detailed in Performance Testing – Bench Section 18 of the submission.

Laboratory test results indicate that the Uritek TC-201 Urine Chemistry Test System can safely and effectively perform with satisfaction when used according to the user manual of the analyzer and the package insert of the strip.

4. Comparison Study

The accuracy of Uritek TC-201 Urine Chemistry Test System was evaluated at three Point-of-Care sites by comparing the data using the predicate. A total of 518 urine specimens were analyzed. Method comparison study results indicate that the intended users were able to obtain comparable testing data when using the Uritek TC-201 Urine Chemistry Test System and the [predicate device](#). The results are summarized in the following table:

	Accuracy	Sensitivity	Specificity
Albumin result	84.9% (n = 518)	97.9% (n=335)	86.9% (n=183)
Creatinine result	83.4% (n = 518)	N/A	N/A
Albumin to Creatinine Ratio	89.9% (n=518)	92.5% (n=255)	93.16% (n=263)

VIII. CONCLUSIONS

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 laboratory test results and the method comparison studies results demonstrate a substantial equivalency on performance between Teco Diagnostics' Uritek TC-201 Urine Chemistry Test System and the predicate device when used appropriately, as outlined in the package insert.

In summary, the results present here support the substantial equivalence to the predicate device.