DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 22, 2014

ACON LABORATORIES, INC.
QIYI XIE
SR. STAFF REGULATORY AFFAIRS/ CLINICAL AFFAIRS
10125 MESA RIM ROAD
SAN DIEGO CA 92121

Re: K142391
Trade/Device Name: MISSION® U120 Ultra Urine Analyzer,
MISSION® Urinalysis Reagent Strips (Microalbumin/creatinine)
MISSION® Liquid Urine Controls,
MISSION® Diptube Urine Controls
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: II
Product Code: JFY, KQO, JIR, JJW
Dated: November 6, 2014
Received: November 7, 2014

Dear Qiyi Xie:

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,

Stayce Beck -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)*
K142391

Device Name
Mission® U120 Ultra Urine Analyzer
Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)
Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls

Indications for Use *(Describe)*
The Mission® U120 Ultra Urine Analyzer is an urinalysis instrument intended for in vitro diagnostic use. It is intended for professional use only at point-of-care locations. The Mission U120 Ultra Urine Analyzer is intended to read Mission® Urinalysis Reagent strips (Microalbumin/Creatinine) for the semi quantitative measurement of Albumin and Creatinine. These measurements are used to assist diagnosis for kidney function.

The Mission® Liquid Urine Controls and Mission® Liquid Diptube Urine Controls are assayed urine controls, intended for use in validating the precision of analyzer reading of urinalysis for the Creatinine and Albumin analytes.

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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7. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Assigned 510(k) number is K142391.

Submitter's Identification:

ACON Laboratories, Inc.
10125 Mesa Rim Road
San Diego, California 92121
Tel.: 858-875-8019
Fax: 858-875-8011

Date Prepared: December 22, 2014

Contact Person:

Qiyi Xie
Senior Staff, Clinical & Regulatory Affairs
Email: qxie@aconlabs.com

Proprietary Name of the Device:

Mission® U120 Ultra Urine Analyzer

Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)

Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls

Common Name:

Urine Chemistry Analyzer

Urinalysis Reagent Strips

Urinalysis Controls (Assayed and Unassayed)

Classification Name:

Class II §21 CFR 862.2900, Automated Urinalysis System

21 CFR 862.1645 Urinary protein or albumin (nonquantitative) test system

21 CFR 862.1225 Creatinine test system

21 CFR 862.1660 Urinalysis Controls (Assayed And Unassayed)

Predicate Device:

Bayer Clinitek Status Analyzer

BAYER HEALTHCARE, LLC

63 North St.

Medfield, MA 02052 -1688

510(k) Number: K031947

CLINITEK Microalbumin Reagent Strips

BAYER CORPORATION

1884 Miles Avenue, P.O. Box 70

Elkhart, IN 46515

510(k) Number: K972706

Biorad Liquicheck Urinalysis control

BIO-RAD

9500 Jeronimo Rd.

Irvine, CA 92618

510(k) Number: k070848

Device Name: Mission® U120 Ultra Urine Analyzer,
Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)
Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls

Proprietary Name	**Classification**	**Product Code**	**Description**	**Common Name**
Mission® U120 Ultra Urine Analyzer	862.2900 Class I	KQO	Automated Urinalysis System	Urine Chemistry Analyzer

Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)	862.1645 – Class I 862.1225 – Class II	JIR JFY	Urinalysis Reagent Strips	Urinalysis Reagent Strips
Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls	862.1660 Class I	JJW	Quality control material (assayed and unassayed)	Urinalysis Controls (Assayed And Unassayed)

Device Description:

The Mission® U120 Ultra Urine Analyzer is a reflectance photometer that analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip.

The Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine) are firm plastic strips that contain two reagent areas to test for Microalbumin (low concentration of albumin) and creatinine in urine. Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine) are to be read by the Mission® U120 Ultra Urine Analyzer.

The Mission® Liquid Urine Controls and Mission® Liquid Diptube Urine Controls are assayed urine controls, intended for use in validating the precision of analyzer reading of urinalysis for the Creatinine and Albumin analytes.

Intended Use:

The Mission® U120 Ultra Urine Analyzer is an urinalysis instrument intended for in vitro diagnostic use. It is intended for professional use only at point-of-care locations. The Mission U120 Ultra Urine Analyzer is intended to read Mission® Urinalysis Reagent strips (Microalbumin/Creatinine) for the semi quantitative measurement of Albumin and Creatinine. These measurements are used to assist diagnosis for kidney function.

The Mission® Liquid Urine Controls and Mission® Liquid Diptube Urine Controls are assayed urine controls, intended for use in validating the precision of analyzer reading of urinalysis for the Creatinine and Albumin analytes.

Tests Principles:

The Mission® U120 Ultra Urine Analyzer is a reflectance photometer that analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip. Using a light emitting diode (LED) as the light source and a CMOS image sensor as a light sensor, the optical system reads the color change in the urine test strips after a sample is applied.

Albumin: The basis for the test is a high affinity sulfonephthalein dye, using the dye binding method to produce any blue color if albumin is present at a constant pH. Results range in color from pale green to aqua blue. In the presence of diluted urine, the pad for the Albumin reading will turn white. This indicates an albumin level ≤ 10 mg/L. Normally, albumin is present in urine at concentrations < 20 mg/L. Results of 20-200 mg/L may indicate micralbuminuria. It is associated with early-stage kidney disease when a small amount of Albumin, also called Microalbumin is consistently present in urine. Clinical albuminuria is indicated by results of >200 mg/L. These levels can be predictive of albumin excretion rates of 30-300 mg/24hours and >300 mg/24hours, respectively. Exercise, acute illness and fever, and urinary tract infections may temporarily elevate urinary albumin excretions.

Creatinine: The peroxidase-like activity of a copper creatinine complex catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'- tetramethylbenzidine to produce a resulting color range from orange through green to blue. Creatinine concentrations of 10-300 mg/dL are normally present in urine**.**

Albumin-to-Creatinine Ratio: It is also called Microalbumin-to-Creatinine ratio test available to assess microalbuminuria. Albumin is normally present in urine at concentrations of <30 mg albumin/g creatinine. Microalbuminuria is indicated at a ratio result of 30-300 mg/g (Abnormal) and clinical albuminuria at a ratio of >300 mg/g (High Abnormal).

Urine Controls: The Mission® Liquid Urine Controls and Mission® Liquid Diptube Urine Controls are assayed urine controls, intended for use in validating the precision of analyzer reading of urinalysis for the Creatinine and Albumin analytes.

Technological Characteristics:

Feature	Mission® U120 Ultra Urine Analyzer
Methodology	Reflectance Photometer
Detection	CMOS Image Sensor
Chemistry	Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)
Throughput	Single Test Mode: 55 tests/hour Continuous Test Mode: 120 tests/hour
Memory	Last 2000 results
Strip Incubation Time	1 minute
PC Port	USB (data communications); (Not connect to PC) Bluetooth Wireless Standard RS232C Port
Capabilities	Internal thermal printer Barcode reader Connector External printer (optional) Barcode reader (optional) RJ45 Ethernet; (optional)
Available Languages on Screen	English and Spanish
Analyzer Operating Conditions	0-40ºC (32-104ºF); ≤85% Relative Humidity (non-condensing)
Strip Operating Conditions	15-30ºC (59-86ºF); 20-80% Relative Humidity (non-condensing)
Power Source	6 AA batteries with 100 tests/6 new batteries; 100- 240 VAC(adapter), (50-60 Hz± 1HZ)
Weight	≤1.66 kg (3.65 lb) without batteries or power supply
Dimensions (L X W X H)	26.0 (L) x 15.0 (W) x 17.5 (H) cm (10.2”x 5.9”x 6.9”)

Display Dimensions (L X W)	Large touch screen Color LCD TFT 640x480, 11.7 (W) x 8.8 (H) cm

Substantial Equivalence:

The Mission® U120 Ultra Urine Analyzer is substantially equivalent to the Bayer Clinitek Status Analyzer (K031947)

Feature	Mission® U120 Ultra Urine Analyzer	Clinitek Status Analyzer (K031947)
Similarities		
Methodology	Reflectance Photometer	Reflectance Photometer
Principle	The U120 Ultra Urine Analyzer measures the intensity of the light reflected from the reagent areas of a urinalysis reagent strip.	The Clinitek Status Analyzer measures the intensity of the light reflected from the reagent areas of a urinalysis reagent strip.
Parameters Detected	Albumin and Creatinine	Albumin and Creatinine
Calculated Parameters	Albumin: Creatinine Ratio	Albumin: Creatinine Ratio
Available Languages on Screen	English and Spanish	English and Spanish
Line Leakage Current	<0.5mA	<0.5mA
Power Source	100- 240 VAC(adapter), (50-60 Hz± 1HZ) 6 AA batteries with 100 tests/6 new batteries;	Input 100-240V ± 20% and 45-65 Hz, output + 9V; Battery powered operation (optional) 6 AA non-rechargeable alkaline batteries
User Interface	Touch Screen based UI	Touch Screen based UI
Weight	≤1.66 kg (3.65 lbs.) without batteries or power supply	1.66 kg (3.65 lbs.)

Differences		
Detection	The Mission® U120 Ultra Urine Analyzer utilizes a CMOS image sensor to measure the intensity of light. The frequency of the light is determined by the LED light source.	The Clinitek Status Analyzer utilizes a CCD (charge coupled device) to measure the intensity of light. The frequency of the light is determined by the LED light source.
Chemistry	Mission® Urinalysis Reagent Strips (Microalbumin/ Creatinine)	CLINITEK Microalbumin Reagent Strips (K972706)
Memory	Last 2000 results	Last 200 results
PC Port	Standard RS232C Port (cable not included), USB Port (cable not included); (Not connect to PC) Bluetooth Wireless	Bidirectional RS232 serial port with standard cable for hooking up to the computer
Capabilities	Internal thermal printer Barcode reader Connector External printer (optional) Barcode reader (optional) RJ45 Ethernet; (optional)	Internal printer (included) External printer (not included) 9-Pin Parallel External Printer Port (included)
Analyzer Operating Conditions	0-40ºC (32-104ºF); ≤85% Relative Humidity (non-condensing)	5-40ºC (41-104ºF); 20%-80% Relative Humidity (non-condensing)
Optimum Operating Conditions	15-30ºC (59-86ºF); 20-80% Relative Humidity (non-condensing)	18-30ºC (64-86ºF) 20-80% Relative Humidity (non-condensing)
Dimensions (L X W X H)	26.0 (L) x 15.0 (W) x 17.5 (H) cm	27.2 (L) x 17.1 (W) x 15.8 (H) cm
Display Dimensions (L X W)	Large touch screen Color LCD TFT 640x480, 11.7 (W) x 8.8 (H) cm	27.2 (L) x 17.1 (W) x 15.8 (H) cm

Characteristic of the Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine) are compared with the Clinitek Microalbumin Reagent Strips (K972706) for instrument reading in the following table:

Area of Comparison	Mission® Urinalysis Reagent Strips (Microalbumin/ Creatinine)	Clinitek Microalbumin Reagent Strips (K972706)
Similarities		
Indications for Use	The Mission Urinalysis Reagent strips (Microalbumin/Creatinine) are intended for the semi quantitative measurement of albumin and creatinine in urine samples using the Mission U120 Ultra Urine Analyzer. These measurements are used to assist diagnosis for kidney function. It is intended for professional use only at point-of-care locations. **The strips are read instrumentally by the Mission® U120 Ultra Urine Analyzer**	Clinitek Microalbumin Reagent Strips are for screening urine specimens to test for small amounts of albumin in urine (microalbuminuria), creatinine in urine, and also determine the albumin-to-creatinine ratio in urine. Clinitek Microalbumin Reagent Strips can be used for screening urine specimens for microalbuminuria as an aid in the detection of patients at risk for developing kidney damage. **The strips are read instrumentally using the Clinitek Status Analyzer (K031947).**
Intended Use	Professional use in point-of-care urine testing	Professional use in point-of-care urine testing
Target Population	Patients of physicians, hospitals, and clinics	Patients of physicians, hospitals, and clinics
Intended Specimen	Urine	Urine
Material Provided	Plastic strips affixed with two separate reagent areas.	Plastic strips affixed with two separate reagent areas.
Albumin Detection Methodology	This test is based on dye binding using a high affinity sulfonephthalein dye. At a constant pH, the development of any blue color is due to the presence of albumin. The resulting color ranges from pale green to aqua blue	This test is based on dye binding using a high affinity sulfonephthalein dye. At a constant pH, the development of any blue color is due to the presence of albumin. The resulting color ranges from pale green to aqua blue

Creatinine Detection Methodology	This test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange through green to blue	This test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange through green to blue
Detection Range	Detects albumin between 10-150 mg/L Detects creatinine between 10-300 mg/dL (0.9 -26.5 mmol/L)	Detects albumin between 10-150 mg/L Detects creatinine between 10-300 mg/dL (0.9 -26.5 mmol/L)
Differences		
Storage	2 to 30ºC	15 to 30ºC

Characteristic of the Mission® Liquid Urine Controls and Mission® Liquid Diptube Urine Controls are compared with the Biorad Liquicheck Urinalysis control (k070848) in the following table:

	Biorad Liquicheck Urinalysis control (k070848)	**Mission Liquid Urine Controls (Dropper and Diptube) (k142391)**
Intended Use	Biorad Liquichek Urinalysis Control is intended for use as assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in this package insert.	The Mission Liquid Urine Controls and Mission Liquid Diptube Urine Controls are assayed urine controls, intended for use in validating the precision of analyzer reading of urinalysis for the Creatinine and Albumin analytes.
Levels	Level-1 and Level-2	Level-1 and Level-2

Reagent	Liquid form. Prepared from human urine with added human erythrocytes, simulated leukocytes, constituents of animal origin, chemicals, preservatives and stabilizers.	Liquid form. Prepared from buffer with added chemicals, preservatives and stabilizers.
Storage	2~8℃	2~8℃
Shelf life	The product is stable until the expired date when stored unopened at 2~8℃. All analytes will be stable for 30days at 2 to 25℃	Unopened controls are stable until the expiration date printed on the bottle label when stored at 2-8°C (36-46°F). All analytes are stable for 30 days at 15-30°C (59-86°F) or until the expiration date at 2-8°C (36-46°F) once opened and stored with the cap on tightly.
Analytes	Bilirubin Blood Casts Clarity Color Creatinine Crystals Glucose hCG Ketones Leukocytes Microalbumin Nitrite Osmolality pH Protein Total Protein-to-Creatinine Ratio RBC Specific Gravity Urobilinogen White Blood cells	Creatinine Microalbumin
Assignment of values	The results printed in the insert were derived from replicate analyses and are specific for this	Expected values were obtained from replicate analysis using three lots of Mission® Urinalysis

	lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of control. Each laboratory should use the results provided only as a reference and establish its own parameters of precision.	Reagent Strips and three Mission® U120 Urine Analyzers for three consecutive days, performed by three operators. Expected values for the Level 1 control solution were assigned as ALB 10mg/L~30mg/L and CRE 10mg/dL~100mg/dL Expected values for level 2 control are ALB 80mg/L~150mg/L and CRE 100mg/dL~300mg/dL.

Discussion of Clinical Accuracy Tests Performed:

Clinical studies were conducted using the Mission® U120 Ultra Urine Analyzer and Mission® Urinalysis Microalbumin/Creatinine Reagent strips. Clinical study data is presented evaluating clinical accuracy of Mission® Urinalysis Microalbumin/Creatinine Reagent strip read by Mission® U120 Ultra Urine Analyzer compared to the predicate: Clinitek Microalbumin 2 Reagent Strips (K972706) read by Clinitek Status Analyzer (K031947).

A total of 429 urine specimens were randomly collected at three clinical sites from patients. Each specimen was tested by ACON U120 Ultra Urine Analyzer with ACON Urinalysis Microalbumin/Creatinine Reagent strip and predicate device. The results are summarized in the table below:

	Accuracy	**Sensitivity**	**Specificity**
Albumin Results with Mission U120 Ultra	86.5% (n=429)	97.6% (n-293)	92.6% (n=136)
Albumin-to-Creatinine Ratio with Mission U120 Ultra	90.7% (n=429)	93.1% (n=233)	94.9% (n=196)

Discussion of Performance Tests Performed:

The performance characteristics of the Mission® U120 Ultra Urine Analyzer to read Mission® Urinalysis Reagent Strips (Microalbumin/ Creatinine) were verified by Precision study, Interference study, Temperature flex study, voltage flex study, SG flex study, pH flex study, Humidity flex study, sensitivity study, stability study, electrical safety testing and EMC testing. Laboratory testing results indicate that the Mission® U120 Ultra Urine Analyzer is robust and

can perform satisfactorily when used according to the "Indication for Use" statement specified in the Instruction Manual and Package Insert of the device.

Precision: The reproducibility of the Mission U120 Ultra Urine Analyzer was evaluated by within run precision and between run precision studies at three POL sites using Control Solutions Level 1 (Neg.), Level 2 (Low) and Level 3 (High). Within run precision study: Each level of the control solution was tested in 20 replicates in one day at each of POL sites. Between run precision study: Each control was tested once at each run, 2 runs per day for 20 days, 3 operators from each site participated the study. The results of within-run and between-run precision studies showed that the agreements with each target concentration were over 99% for the U120 Ultra.

Interference Study: Three levels of urine controls were spiked with the possible interfering substances one at a time to two concentrations following EP7-A2: Level 2 (common pathological value) and level 1 (5 times lower than level 2). Each sample was tested in triplicates. Results are summarized in the table below:

Substances	Conc. Tested	Interference on the Testing Result	
		Result of Albumin	Result of Creatinine
Human IgG	25 mg/dL	False High	N/A
Sodium Bicarbonate	1500 mg/dL	False High	N/A
Potassium Chloride	1500 mg/dL	False Low	N/A
Hemoglobin	10 mg/dL	False High	False High
Blood	0.05%	False High	False High

Conclusion:

The laboratory testing results and clinical studies demonstrate that the Mission® Urinalysis Reagent Strips (Microalbumin/ Creatinine) read by Mission® U120 Ultra Urine Analyzer is safe, effective and easy-to-use and such is substantially equivalent to the Clinitek Microalbumin Reagent Strips (K972706) read by Clinitek Status Analyzer (K031947), currently sold on the U.S. market for professional use at point-of-care locations.