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

October 7, 2016

ARKRAY, INC.
NAVEEN THURAMALLA
VICE PRESIDENT, REGULATORY AFFAIRS
5182 76TH STREET
EDINA MN 55439

Re: K160062
Trade/Device Name: AUTION ELEVEN Semi-Automated Urinalysis System
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: II
Product Code: JIL, JIO, KQO, CDM, CEN, JIN, JIR, JJB, JMT, LJX, JRE
Dated: August 29, 2016
Received: August 30, 2016

Dear Naveen Thuramalla:

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,

Courtney H. Lias -S

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)*
k160062

Device Name
AUTION ELEVEN Semi-Automated Urinalysis System

Indications for Use *(Describe)*

The AUTION ELEVEN Semi-Automated Urinalysis System provides a qualitative and semi-quantitative measurements for glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrites, leukocytes, specific gravity and color tone in urine specimens. The system is intended for in vitro diagnostic use in screening patient populations found in clinical laboratories.

The AUTION ELEVEN Semi-Automated Urinalysis System consists of the following:

- AUTION ELEVEN model AE-4022 Urine Analyzer (device component)
- AUTION Sticks 10EA Test Strips (reagent component)

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

This 510(k) Summary of the AUTION ELEVEN Semi-Automated Urinalysis System is submitted in compliance of 21 CFR 807.92 for the purposes of safety and effectiveness.

510(k) Number:	k160062
Date Prepared:	October 06, 2016
Establishment:	ARKRAY Inc. Yousuien-Nai 59 Gansuin-Cho, Kamigyo-Ku Kyoto 602-0008, Japan Establishment Registration Number: 9611444
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Device Name

Trade Name: AUTION ELEVEN Semi-Automated Urinalysis System

Common Name: Automated Urinalysis System

510(k) Number: k160062

Table 1: Regulatory Information

Regulation: 21 CFR Section	Product Code	Classification	Description
862.1340	JIL	Class II	Glucose (Urinary, Non-Quantitative)
864.6550	JIO	Class II	Blood, Occult, Colorimetric, In Urine
862.2900	KQO	Class I	Automated Urinalysis System
862.1785	CDM	Class I	Urobilinogen (Urinary Non-Quant.)
862.1550	CEN	Class I	pH (Urinary, Non-Quant.)
862.1435	JIN	Class I	Ketones (Urinary, Non-Quant.)
862.1645	JIR	Class I	Protein or Albumin (Urinary, Non-Quant.)
862.1115	JJB	Class I	Urinary Bilirubin & Its Conjugates (Urinary, Non-Quant.)
862.1510	JMT	Class I	Nitrite (Urinary, Non-Quant.)
864.7675	LJX	Class I	Test, Urine Leukocyte
862.2800	JRE	Class I	Specific Gravity

Predicate Devices

AUTION MAX AX-4030 Urinalysis System (K093098)

Intended Use

The AUTION ELEVEN Semi-Automated Urinalysis System provides a qualitative and semi-quantitative measurements for glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrites, leukocytes, specific gravity and color tone in urine specimens. The system is intended for in vitro diagnostic use in screening patient populations found in clinical laboratories.

The AUTION ELEVEN Semi-Automated Urinalysis System consists of the following:

- AUTION ELEVEN model AE-4022 urine analyzer (device component)
- AUTION Sticks 10EA test strips (reagent component)

Device Description

The AUTION ELEVEN Semi-Automated Urinalysis System provides a qualitative and semi-quantitative measurement for glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrites, leukocytes, specific gravity and color tone. The system is intended for in vitro diagnostic use in screening patient populations found in clinical laboratories. The AUTION ELEVEN Semi-Automated Urinalysis System consists of AUTION ELEVEN model AE-4022 urine analyzer and AUTION Sticks 10EA test strips.

The AUTION sticks 10EA consist of a plastic strip containing 10 pads impregnated with chemicals specific for the determination of a particular analyte. The chemical reaction with the urine results in a color change which is measured by the AUTION ELEVEN AE-4022 device, resulting in a display and print out indicating analyte concentration. The AUTION ELEVEN technology provides fast results that can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

The semi-automated nature of the device requires the user to dip an AUTION Stick 10EA test strip into a patient urine specimen and place it on the instrument. The instrument processes the test strip, allowing 60 seconds for the chemical reactions to occur on the test strip reagent pads. After 60 seconds, the device measures the amount of reflectance generated from each reagent pad and converts the reflectance measurements to qualitative and semi-quantitative results for physician use.

Substantial Equivalence

Table 2: Substantial Equivalence

#	Element of Comparison	AUTION MAX AX-4030 (Predicate)	Claimed Substantial Equivalent Device, AUTION ELEVEN Semi-Automated Urinalysis System	AUTION ELEVEN Comparison
1	Proprietary Name	AUTION MAX	AUTION ELEVEN	N/A
2	510(k) Number	K093098 (2009)	K160062	N/A
3	Class	Class II (*Blood and Glucose analytes raise system to Class II / 510(k) required*)	Class II (*Blood and Glucose analytes raise system to Class II / 510(k) required*)	SAME
4	Data Type	Qualitative, Semi-Quantitative	Qualitative, Semi-Quantitative	SAME
5	Location	Clinical Laboratory	Clinical Laboratory	SAME
6	Medical Device/IVD	Medical Device/IVD	Medical Device/IVD	SAME
7	Specimen	Human Urine	Human Urine	SAME
8	Analytes	Glucose Protein Bilirubin Urobilinogen pH Blood Ketones Nitrite Leukocyte Specific Gravity	Glucose Protein Bilirubin Urobilinogen pH Blood Ketones Nitrite Leukocyte Specific Gravity	SAME
9	Color Tone Detection	23 color tones using 3 wavelengths (red, green and blue); executed by a color tone unit with a different calculation	23 color tones using 4 wavelengths (red, green, blue, infrared); executed by the optical unit	Testing demonstrates color tone detection.

#	Element of Comparison	AUTION MAX AX-4030 (Predicate)	Claimed Substantial Equivalent Device, AUTION ELEVEN Semi-Automated Urinalysis System	AUTION ELEVEN Comparison
10	Color Tone correction	Calculation to mitigate urine color interference	Calculation to mitigate urine color interference	Testing shows color does not inhibit results.
11	Abnormal Color Marker (!) (ketone, urobilinogen, bilirubin)	Calculations based on wavelengths 430nm, 500nm, 565nm, and 635nm	Calculations based on wavelengths 430nm, 565nm, and 635nm	Same formula comparing the analyte pad reflectance ratio of 2 colors divided by the reference pad reflectance ratio of the same 2 colors.
12	Turbidity/ Clarity	Determines turbidity	Does not determine turbidity. Option available for user to enter level of clarity per laboratory professional education.	Device does not determine this optional parameter.

#	Element of Comparison	AUTION MAX AX-4030 (Predicate)	Claimed Substantial Equivalent Device, AUTION ELEVEN Semi-Automated Urinalysis System	AUTION ELEVEN Comparison
13	Reagent Test Strips	AUTION Sticks 9EB: (1) No specific gravity reagent pad (uses Refractometer); (2) Uses blank pad for correction due to urine color; *different calculation* (3) Has black marker for model distinction by device	AUTION Sticks10EA: (1) Has specific gravity reagent pad; (2) Uses blank pad for correction due to urine color; (3) Has black marker for model distinction by device	SAME as AUTION MAX for all reagent pads except specific gravity. SAME chemical reactions, as AUTION MAX. AUTION ELEVEN was compared to AUTION MAX for 9 analytes, as the more recent predicate, and was compared to AUTION JET (k030600) for specific gravity only.
14	Quality Control Solution	Commercial urine analyzer Control Solution	Commercial urine analyzer Control Solution	SAME

#	Element of Comparison	AUTION MAX AX-4030 (Predicate)	Claimed Substantial Equivalent Device, AUTION ELEVEN Semi-Automated Urinalysis System	AUTION ELEVEN Comparison
15	Check Strips – for quality control of device optical unit's light intensity	AUTION Check Strips (provided with device)	AUTION Check Strips (provided with device)	SAME
16	Method of device chemistry determination	Colorimetric Reflectometry of reagent chemical reaction with analyte for all analytes **except Refractometry for specific gravity*	Colorimetric Reflectometry of reagent chemical reaction with analyte for all analytes	SAME as AUTION MAX for all reagent pads except specific gravity. SAME as AUTION JET (k030600) for specific gravity.
17	Barcode Reader Possible/Not Required	Yes	Yes	SAME
18	Urine mixed for homogeneity	By hand and aspirator	By hand	Clinical Testing shows that AUTION MAX and AUTION
19	Urine applied to reagent pad	Automatic pipette-applied	Hand-dipped for 2 seconds	

#	Element of Comparison	AUTION MAX AX-4030 (Predicate)	Claimed Substantial Equivalent Device, AUTION ELEVEN Semi-Automated Urinalysis System	AUTION ELEVEN Comparison
20	Timing between urine application and determination	Automatic	Controlled by Human count/sound alarms + automation	ELEVEN devices perform similarly and there is no additional effect on safety and effectiveness.
21	Timing of reagent reaction	Approximately 60 seconds	Approximately 60 seconds	SAME
22	Result determination	Automatic	Automatic	SAME
23	Rank Table	Includes Qualitative and Semi-Quantitative Ranks	Includes Qualitative and Semi-Quantitative Ranks; Semi-Quantitative ranks match Qualitative ranks in number	SAME; All Semi-Quantitative ranks within the respective Qualitative rank are combined. The ranks align with predicate Qualitative ranks and their respective Semi-Quantitative concentration limits although only 1 Semi-

#	Element of Comparison	AUTION MAX AX-4030 (Predicate)	Claimed Substantial Equivalent Device, AUTION ELEVEN Semi-Automated Urinalysis System	AUTION ELEVEN Comparison
				Quantitative concentration reference is provided where there may be 2-3 for a predicate Semi-Quantitative rank.
24	Software-Controlled	Yes	Yes	SAME
25	Printed Data Report	Yes	Yes	SAME
26	Measurement Wavelengths for Analytes	Dual wavelength measurement using 565, 635, 760 nm (Except blood, which uses only 635 nm)	Dual wavelength measurement using 565, 635, 760 nm (Except blood, which uses only 635 nm)	SAME
27	Processing Speed	225 samples/hr	514 samples/hr	Result determination time remains the same, so no difference in technology or chemistry – just throughput.
28	Memory Capacity	2500 tests	520 tests	Testing for electronic safety and compatibility.
29	Crystal (LC) Display	Yes	Yes	
30	Built-in printer	Yes	Yes	
31	External output	RS-232C/ Ethernet	RS-232C/ Ethernet	

#	Element of Comparison	AUTION MAX AX-4030 (Predicate)	Claimed Substantial Equivalent Device, AUTION ELEVEN Semi-Automated Urinalysis System	AUTION ELEVEN Comparison
32	Barcode Specifications	NW-7, CODE39, code 128, ITF; On unit	NW-7, CODE39, code 128, ITF; hand held type	
33	Voltage Supply	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz; use adapter 12 VDC 3A	
34	Dimensions (mm)	530 (w) x 530(d) x 530 (h)	210 (w) x 328 (d) x 164 (h)	N/A
35	Linearity	Yes	Yes	SAME
36	Sensitivity	Yes	Yes	SAME
37	Interfering Substances	Yes	Yes	SAME
38	Detection Limit/ Specificity	Yes	Yes	SAME
39	Accuracy by Comparison	Yes	Yes	SAME
40	Precision	Yes	Yes	SAME
41	Color Tone Detection	Yes	Yes	SAME
42	Color Tone Correction	Yes	Yes	SAME
43	Electrical Safety	Yes	Yes	Slight differences per specifications. Testing ensures safety and efficacy.
44	Radiofrequency	Yes	Yes	
45	Electrical Compatibility	Yes	Yes	
46	Device Software	Yes	Yes	
47	Stability-Closed Bottle	Yes	Yes	SAME
48	Stability-Open Bottle	Yes	Yes	

Standards Referenced

Clinical and Laboratory Standards Institute. (2014). EP05-A3 Vol 34 No.13 *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Ed.*

Clinical and Laboratory Standards Institute. (2003). EP06-*A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.*

Clinical and Laboratory Standards Institute. (2005). EP07-A2 *Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition.*

Clinical and Laboratory Standards Institute. (2010). EP09-A2-IR Vol. 30 No. 17 *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition.*

Clinical and Laboratory Standards Institute. (2009). GP-16-A2 21 No.19 *Urinalysis; Approved Guideline – Third Edition*.

Clinical and Laboratory Standards Institute. (2012). EP17-A2 Vol 32 No.8 *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline- Second Edition.*

Test Principle

The AUTION ELEVEN Semi-Automated Urinalysis System device model AE-4022 uses 4 LED wavelengths to accurately read AUTION 10EA Stick test strips which are impregnated with chemicals to induce the reactions shown below upon contact with particular analytes in urine. Three (3) of the wavelengths read the analyte interaction while the fourth wavelength is used for color tone detection and correction.

Glucose: Glucose oxidase reaction.

$$\text{Glucose} \xrightarrow{\text{GOD}} \text{Gluconic acid} + H_2O_2$$

$$H_2O_2 + \text{4-AAP} + \text{1-Naphthol-3,6-disulfonic acid} \xrightarrow[\text{oxidation}]{\text{POD}} \text{Quinone imine dye (purple color)}$$

Protein: Protein-error reaction.

$$\text{Protein} + \text{pH indicator} \xrightarrow{\text{acid}} \text{pH indicator changes to a cyan color}$$

Bilirubin: Azo-coupling reaction.

$$\text{2-Methyl-5-nitroaniline} + \text{Sodium nitrite} \xrightarrow[\text{diazo reaction}]{\text{acid}} \text{Diazonium salt}$$

$$\text{Bilirubin} + \text{Diazonium salt} \xrightarrow[\text{coupling reaction}]{\text{acid}} \text{Azo dye (reddish brown color)}$$

Urobilinogen: Azo-coupling reaction.

$$\text{Urobilinogen} + \text{Diazonium salt} \xrightarrow[\text{coupling reaction}]{\text{acid}} \text{Azo dye (reddish brown color)}$$

pH: pH indicator.

$$H^+ + \text{mixed pH indicator} \longrightarrow \text{mixed pH indicator shows range of colors covering the urinary pH range (yellow - cyan color)}$$

Specific Gravity: Cation extraction.

$$\text{Cation} + \text{D-2-EHPA} + \text{pH indicator} \xrightarrow{\text{cation extraction}} \text{color reaction of pH indicator (cyan - yellow color)}$$

Blood: Activity measurement of pseudoperoxidase in hemoglobin.

$$\text{CHP} + \text{TMBZ} \xrightarrow[\text{pseudoperoxidase action}]{\text{hemoglobin}} H_2O + \text{Cumene} + \text{Oxidation dye (cyan color)}$$

Ketones: Legal reaction.

$$\text{Ketones} + \text{Sodium nitroprusside} \xrightarrow{\text{alkaline}} \text{Ketones complex (purple color)}$$

Nitrite: Griess reaction.

$$\text{Nitrite} + \text{Sulfanilamide} \xrightarrow{\text{acid}} \text{Diazo-compound} + \text{NEDA-2HCl} \xrightarrow[\text{coupling reaction}]{\text{acid}} \text{Azo dye (pink color)}$$

Leukocytes: Measurement of leukocyte esterase activity.

$$\text{TAI} \xrightarrow[\text{hydrolysis}]{\text{esterase from leukocytes}} \text{Indoxyl} + \text{MMB} \xrightarrow{\text{coupling reaction}} \text{Azo dye (purple color)}$$

Performance Characteristics

Bench testing and clinical testing were done in order to verify that the above differences are minor in nature and do not affect the overall performance, safety, or effectiveness of the proposed device compared to the predicate device.

Precision Results

Each analyte was tested at 3 clinical sites using 3 operators on 3 devices for a minimum of 20 days. Three (3) levels of quality controls were used to attain results at negative, mid-level positive and high-positive analyte ranges. Two (2) levels of commercial controls were used to obtain the 3 levels, using dilutions and spiking materials as needed to obtain the highest and mid-level controls for testing of all the analyte ranks.

Table 3: Precision Results

	Repeatability		**Reproducibility**	
Analyte	Exact match %	+/- 1 Color Block %	Exact match %	+/- 1 Color Block %
Glucose	98%	100%	99%	100%
Protein	100%	100%	100%	100%
Bilirubin	99%	100%	99%	100%
Urobilinogen	99%	100%	100%	100%
pH	98%	100%	99%	100%
Specific gravity	96%	100%	97%	100%
Blood	99%	100%	100%	100%
Ketones	100%	100%	100%	100%
Nitrite	100%	100%	100%	100%
Leukocytes	100%	100%	100%	100%

Comparison Study Results

A Method Comparison study was performed at 3 sites to compare the AUTION ELEVEN Semi-Automated Urinalysis System against 2 commercially available urinalysis predicates, 1 semi-automated urine analyzer was used for specific gravity comparison and one fully-automated urine analyzer was used to compare all the rest of the analytes.

Each site collected urine patient samples from their clinical laboratory or obtained them from nearby hospitals. Urine samples were collected and refrigerated within 2 hours of collection, for up to 24 hours of refrigeration prior to clinical study testing. For inclusion into the study, the samples collected had to be positive for at least one of the chemistry analytes present on the AUTION Stick 10EA urinalysis strip

Data from each site was combined for the analysis. Accuracy (percent agreement) results are shown below.

Table 4: Method Comparison Results

Analyte	Number of samples	Percent Positive Samples	Exact Agreement with Predicate	95% CI	Agreement within ± 1 color block
Glucose	2199	16%	98%	97.5 - 98.6	100%
Protein	563	56%	86%	83.2 - 89.1	100%
Bilirubin	2323	8%	100%	99.1 - 99.7	100%
Urobilinogen	2308	12%	98%	94.7 - 96.4	100%
pH	2307	100%	89%	88.3 - 90.9	100%
Specific Gravity	548	100%	81%	77.9 - 84.6	99%
Blood	548	45%	92%	89.2 - 94	100%
Ketones	2221	28%	96%	95.1 - 96.8	100%
Nitrite	2209	6%	99%	99.6 - 98.8	100%
Leukocyte	548	40%	92%	89 - 93.8	100%

Interfering Substances

Table 5: Interferent Results

Analyte	Interferent	Concentration	Result
Glucose	Ascorbic acid	>50 mg/dL	False negative (-2 to -3 color block change)
	pH	<pH4	False positive (+2 color block change)
Protein	Hemoglobin	>20 mg/dL	False positive (+2 color block change)
Bilirubin	Urobilinogen	>8 mg/dL	False positive (+1 color block change)
Urobilinogen	Bilirubin	>3 mg/dL	False positive (+1 color block change)
pH	N/A		
Specific Gravity	pH	<pH4	Elevated (+2 color block change)
	Albumin	>300 mg/dL	Elevated (+2 color block change)
	Ammonium chloride	>200 mg/dL	Elevated (+2 color block change)
Blood	Substances such as MESNA that contain	>50 mg/dL	False negative (-3 color block change)
Ketones	Substances such as MESNA that contain	>5 mg/dL	False positive (+2 to +5 color block change)
Nitrite	N/A		
Leukocytes	Glucose	>200 mg/dL	False negative (-2 color block change)
	Albumin	>300 mg/dL	False negative (-2 color block change)
	pH	<pH4	False negative (-2 color block change)

Detection Limits/Sensitivity Results

Listed below are thresholds by which the analyte concentration/level is met for the higher rank at least 50% of the time.

Table 6: Detection Limits

Analyte	Qualitative Rank	Semi-Quantitative Rank	Actual Concentration	Percent in Rank	Units
Glucose	-	NEG	0	100%	mg/dL
	±	30	30	100%	mg/dL
	1+	70	60	100%	mg/dL
	2+	150	125	100%	mg/dL
	3+	300	250	100%	mg/dL
	4+	1000	750	87%	mg/dL
Protein	-	NEG	0	100%	mg/dL
	±	10	10	100%	mg/dL
	1+	30	25	63%	mg/dL
	2+	100	85	100%	mg/dL
	3+	300	250	100%	mg/dL
	4+	1000	800	97%	mg/dL
Bilirubin	-	NEG	0	100%	mg/dL
	1+	0.5	0.5	50%	mg/dL
	2+	2	1.9	53%	mg/dL
	3+	6	5.3	87%	mg/dL
	4+	14	12	100%	mg/dL
Urobilinogen	NORM	NORM	0	100%	mg/dL
	1+	2	2.0	100%	mg/dL
	2+	4	3.5	50%	mg/dL
	3+	8	6.5	100%	mg/dL
	4+	16	14	100%	mg/dL
pH	***N/A***	5.0	5.0	100%	***N/A***
		5.5	5.3	100%	
		6.0	5.8	100%	
		6.5	6.3	87%	
		7.0	6.8	100%	
		7.5	7.3	87%	
		8.0	7.8	97%	
		8.5	8.3	50%	
		9.0	8.9	50%	

Analyte	Qualitative Rank	Semi-Quantitative Rank	Actual Concentration	Percent in Rank	Units
Specific Gravity	***N/A***	< 1.005	1.005	100%	***N/A***
		1.010	1.008	60%	
		1.015	1.013	90%	
		1.020	1.019	100%	
		1.025	1.023	97%	
		>1.030	1.028	83%	
Blood	-	NEG	0	100%	mg/dL
	±	0.03	0.023	100%	mg/dL
	1+	0.06	0.05	97%	mg/dL
	2+	0.20	0.18	87%	mg/dL
	3+	1.00	0.9	50%	mg/dL
Ketone	-	NEG	0	100%	mg/dL
	±	5	4	100%	mg/dL
	1+	10	7.5	100%	mg/dL
	2+	40	30	100%	mg/dL
	3+	80	70	73%	mg/dL
	4+	150	130	63%	mg/dL
Nitrite	-	***N/A***	0	100%	***N/A***
	1+		0.075	50%	
	2+		0.3	100%	
Leukocytes	***N/A***	NEG	0	100%	Leu/µL
		25	25	100%	Leu/µL
		75	50	77%	Leu/µL
		250	180	97%	Leu/µL
		500	390	83%	Leu/µL

Linearity Results

Table 7: Linearity

Analyte	Qualitative Rank	Semi-Quantitative Rank	Concentration /Level Tested	Exact Match	± 1 Color Block
Glucose	-	NEG	0 mg/dL	100% (21/21)	100% (21/21)
	±	30	45 mg/dL	90.5% (19/21)	100% (21/21)
	1+	70	85 mg/dL	100% (21/21)	100% (21/21)
	2+	150	170 mg/dL	100% (21/21)	100% (21/21)
	3+	300	340 mg/dL	100% (21/21)	100% (21/21)
	4+	1000	2700 mg/dL	100% (21/21)	100% (21/21)
Protein	-	NEG	0 mg/dL	100% (21/21)	100% (21/21)
	±	10	15 mg/dL	100% (21/21)	100% (21/21)
	1+	30	30 mg/dL	100% (21/21)	100% (21/21)
	2+	100	120 mg/dL	100% (21/21)	100% (21/21)
	3+	300	480 mg/dL	100% (21/21)	100% (21/21)
	4+	1000	1000 mg/dL	100% (21/21)	100% (21/21)
Bilirubin	-	NEG	0 mg/dL	100% (21/21)	100% (21/21)
	1+	0.5	1.5 mg/dL	100% (21/21)	100% (21/21)
	2+	2	3 mg/dL	100% (21/21)	100% (21/21)
	3+	6	6 mg/dL	100% (21/21)	100% (21/21)
	4+	14	14 mg/dL	100% (21/21)	100% (21/21)
Urobilinogen	NORM	NORM	normal	100% (21/21)	100% (21/21)
	1+	2	3 mg/dL	100% (21/21)	100% (21/21)
	2+	4	5 mg/dL	100% (21/21)	100% (21/21)
	3+	8	10 mg/dL	95.2% (20/21)	100% (21/21)
	4+	16	20 mg/dL	100% (21/21)	100% (21/21)
pH	***N/A***	5	5.0	100% (21/21)	100% (21/21)
		5.5	5.5	100% (21/21)	100% (21/21)
		6	6.0	100% (21/21)	100% (21/21)
		6.5	6.5	100% (21/21)	100% (21/21)
		7	7.0	95.2% (20/21)	100% (21/21)
		7.5	7.5	100% (21/21)	100% (21/21)
		8	8.0	100% (21/21)	100% (21/21)
		8.5	8.4	95.2% (20/21)	100% (21/21)
		9	9.0	100% (21/21)	100% (21/21)
Specific Gravity	***N/A***	< 1.005	1.000	100% (21/21)	100% (21/21)
		1.010	1.010	100% (21/21)	100% (21/21)
		1.015	1.015	95.2% (20/21)	100% (21/21)
		1.020	1.020	90.5% (19/21)	100% (21/21)
		1.025	1.025	100% (21/21)	100% (21/21)
		>1.030	1.035	100% (21/21)	100% (21/21)

Analyte	Qualitative Rank	Semi-Quantitative Rank	Concentration /Level Tested	Exact Match	± 1 Color Block
Blood	-	NEG	0 mg/dL	100% (21/21)	100% (21/21)
	±	0.03	0.03 mg/dL	100% (21/21)	100% (21/21)
	1+	0.06	0.08 mg/dL	100% (21/21)	100% (21/21)
	2+	0.20	0.6 mg/dL	95.2% (20/21)	100% (21/21)
	3+	1.00	1.3 mg/dL	100% (21/21)	100% (21/21)
Ketone	-	NEG	0 mg/dL	100% (21/21)	100% (21/21)
	±	5	5 mg/dL	100% (21/21)	100% (21/21)
	1+	10	15 mg/dL	100% (21/21)	100% (21/21)
	2+	40	60 mg/dL	100% (21/21)	100% (21/21)
	3+	80	120 mg/dL	90.5% (19/21)	100% (21/21)
	4+	150	240 mg/dL	100% (21/21)	100% (21/21)
Nitrite	-	***N/A***	0 mg/dL	100% (21/21)	100% (21/21)
	1+		0.1 mg/dL	100% (21/21)	100% (21/21)
	2+		0.8 mg/dL	100% (21/21)	100% (21/21)
Leukocytes	***N/A***	NEG	0 Leu/µL	100% (21/21)	100% (21/21)
		25	25 Leu/µL	100% (21/21)	100% (21/21)
		75	75 Leu/µL	95.2% (20/21)	100% (21/21)
		250	250 Leu/µL	100% (21/21)	100% (21/21)
		500	520 Leu/µL	100% (21/21)	100% (21/21)

Proposed Labeling

Labeling adequately communicates device intended use, safety precautions and directions for use. It satisfies 21 CFR Part 809.10 for in vitro diagnostic devices.

Conclusion

Bench Testing

Bench testing evaluations were used to verify performance characteristics of the AUTION ELEVEN Semi-Automated Urinalysis System. Bench testing evaluations included: linearity, sensitivity, interfering substances, detection limit/specificity, electrical compatibility and safety, radiofrequency compatibility, device software validation, and test strip shelf life and stability. In all instances, results from bench testing met pre-determined acceptance criteria and support a determination of substantial equivalence.

Clinical Testing

A precision study was performed on each analyte across 3 sites with 3 operators (1 per site) and 3 devices using 3 levels of quality control solutions per analyte to evaluate repeatability and reproducibility. A Method Comparison study was performed at a predetermined number of sites with 8395 tests of individual analytes including both natural and spiked samples. The overall conclusion from the clinical evaluation is that the results are

acceptable and support a determination of substantial equivalence without additional risk to safety and efficacy.

Based upon the intended use, comparison with the previously cleared predicate devices, technology similarities, and bench and clinical data, the AUTION ELEVEN Semi-Automated Urinalysis System is substantially equivalent to the predicate devices, AUTION MAX AX-4030 Fully-Automated Urinalysis System.