



April 13, 2023

ARKRAY Inc.
Daya Ranamukhaarachchi
VP/Scientific and Regulatory Affairs
5198 West 76th Street
Minneapolis, MN 55439

Re: K193514

Trade/Device Name: AUTION MAX AX-4060 Urinalysis System
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: Class II
Product Code: JIL, JIO, KQO, CDM, JIR, JMT, LJX, JJB, CEN, JIN
Dated: October 19, 2022
Received: October 20, 2022

Dear Daya Ranamukhaarachchi:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Paula V.
Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Division Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K193514

Device Name
AUTION MAX AX-4060 Urinalysis System

Indications for Use (Describe)

The AUTION MAX AX-4060 Urinalysis System (AUTION MAX) is comprised of the AUTION MAX AX-4060 automated urine analyzer and AUTION Sticks 9EB multi-parameter test strips.

The AUTION MAX AX-4060 urine analyzer, when used with AUTION Sticks 9EB test strips is a fully automated urinalysis system intended for the in vitro qualitative or semi-quantitative measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes, turbidity, and color. The test results of these parameters can be used in the evaluation of kidney, urinary, liver and other metabolic disorders. This system is intended to be used by trained operators in clinical laboratories.

AUTION Sticks 9EB test strips are test strips for the in vitro qualitative or semi-quantitative measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, and leukocytes with the AUTION MAX AX-4060 urine analyzer. The test results of these parameters can be used in the evaluation of kidney, urinary, liver and other metabolic disorders.

Special conditions for use statements:

Prescription use only.

AUTION Sticks 9EB test strips are not to be read visually.

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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5. 510(k) SUMMARY

The 510(k) Summary is included on the following pages.

510(k) Summary

This 510(k) Summary of the AUTION MAX AX-4060 Urinalysis System is submitted in compliance with 21 CFR807.92 for the purposes of safety and effectiveness.

Date Prepared: October 19, 2022

Establishment: ARKRAY Factory Inc.

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Device Name:

Trade Name: 1. AUTION MAX AX-4060 Urinalysis System

Common Name: 1. Automated Urinalysis System
2. Urinalysis Test Strip

Predicate Device:

1. AUTION MAX AX-4030 Fully Automated Urinalysis System (K093098)
2. AUTION Sticks 9EB (K013783)

Regulatory Information:

Regulatory Classification for Urinalysis system and each of the tests are listed in **Table 1**.

Table 1. Regulatory Classification for AUTION MAX AX-4060 Urinalysis System

Test Description	Product Code	Device Class	Regulation	Device Panel
Automated urinalysis system	KQO	Class I	21 CFR 862.2900	75 Chemistry
Glucose, urinary, nonquantitative	JIL	Class II	21 CFR 862.1340	75 Chemistry
Blood, occult, colorimetric, in urine	JIO	Class II	21 CFR 864.6550	81 Hematology
Urobilinogen, urinary, non-quantitative	CDM	Class I	21 CFR 862.1785	75 Chemistry
Protein or albumin, urinary, nonquantitative	JIR	Class I	21 CFR 862.1645	75 Chemistry
Nitrite, nonquantitative	JMT	Class I	21 CFR 862.1510	75 Chemistry
Leukocyte, peroxidase test	LJX	Class I	21 CFR 864.7675	81 Hematology
Bilirubin and its conjugates, urinary, non-quantitative	JJB	Class I	21 CFR 862.1115	75 Chemistry
pH, urinary, nonquantitative	CEN	Class I	21 CFR 862.1550	75 Chemistry
Ketones nonquantitative	JIN	Class I	21 CFR 862.1435	75 Chemistry

Intended Use

The AUTION MAX AX-4060 Urinalysis System (AUTION MAX) is comprised of the AUTION MAX AX-4060 automated urine analyzer and AUTION Sticks 9EB multi-parameter test strips.

The AUTION MAX AX-4060 urine analyzer, when used with AUTION Sticks 9EB test strips is a fully automated urinalysis system intended for the in vitro qualitative or semi-quantitative measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes, turbidity, and color. The test results of these parameters can be used in the evaluation of kidney, urinary, liver and other metabolic disorders. This system is intended to be used by trained operators in clinical laboratories.

AUTION Sticks 9EB test strips are test strips for the in vitro qualitative or semi-quantitative

measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, and leukocytes with the AUTION MAX AX-4060 urine analyzer. The test results of these parameters can be used in the evaluation of kidney, urinary, liver and other metabolic disorders.

Special conditions for use statements:

Prescription use only.

AUTION Sticks 9EB test strips are not to be read visually.

Device Description

The AUTION MAX AX-4060 Urinalysis System is a fully automated urine analyzer that provides a semi-quantitative or qualitative measurement for glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrites, leukocytes, specific gravity, turbidity, and color tone. The AUTION MAX AX-4060 Urinalysis System consists of AUTION MAX AX-4060 urine analyzer and AUTION Sticks 9EB test strips.

The AUTION Sticks 9EB test strips consist of a plastic strip containing 9 dry chemistry reagent pads impregnated with chemical substances for the determination of the above analytes in urine. These substances if present in urine leads to a chemical reaction that results in a color change, which is measured by the AUTION MAX AX-4060 urine analyzer based on spectrophotometry. In addition, three additional parameters, specific gravity, turbidity, and color tone are directly measured based on reflectance refractometry, transmitted and scattered light measurements.

Substantial Equivalence

AUTION MAX AX-4060 Urinalysis System was developed as the successor to the predicate device AUTION MAX AX-4030 Urinalysis System. The device uses the same intended use claims as the predicate. The AX-4060 system utilizes the same principles and technology and shares the identical 9EB test strips for measuring the same urine analytes in a semi-quantitative or qualitative manner similar to the predicate device. Some important device parts such as LED and Nozzle dispensing units were changed in the AX-4060 System due to a change in manufacturing source and the device was optimized to generate similar performance to the predicate device.

As described in the Performance Characteristics Section below, the verification and validation (bench and clinical) testing demonstrated substantial equivalence for the AX-4060 System with AUTION Sticks 9EB test strips to the predicate device. Bench testing supports that the AX-4060 System performs to meet specifications for precision, linearity, limits of detection (LOD), sensitivity, carryover and interference. Additionally, software testing, electrical safety testing and EMC testing also met performance criteria.

A list of similarities and differences between the proposed device and the predicate device is provided in **Table 2**.

Table 2. Substantial Equivalence comparison between AUTION MAX AX-4060 Urinalysis System and AUTION MAX AX-4030 Urinalysis System

COMPONENT/ CHARACTERISTIC	PROPOSED	PREDICATE
510(k) Number	To Be Determined	K093098
Device	AUTION MAX AX-4060 Urinalysis System	AUTION MAX AX-4030 Urinalysis System
Similarities between Proposed and Predicate Devices		
Device Type	Automated Urinalysis System	Same
FDA Product Code	KQO, JIL, JIO	Same
FDA Authorized Use	Prescription Use	Same
FDA Classification	Class II	Same
Specimen Type/Measurement Object	Urine	Same
Reagent (Chemical Test Strips)	AUTION Sticks 9EB	Same
Measurement Items	GLU (Glucose), PRO (Protein), BIL (Bilirubin), URO (Urobilinogen), PH (pH), BLD (Blood), KET (Ketones), NIT (Nitrite), LEU (Leukocytes), S.G. (Specific gravity), turbidity, and color tone.	Same
Sample Consumption	Max. 0.90 mL	Same
Required Sample Volume	Min. 2.0 mL	Same
Test Strip Reaction Time	Approx. 60 seconds	Same
Test Strip Storage	Two test strip storage compartments, each of which can contain different test strips	Same
Test Strip Storage Capacity	Maximum 200 test strips × two storage compartments	Same
Max. Processing Speed	225 samples/hour	Same
Built-in Printer	58-mm width printer paper (24 digits)	Same

COMPONENT/ CHARACTERISTIC	PROPOSED	PREDICATE
Memory Capacity	Normal and STAT measurements: 2500 tests Control measurement: 200 tests Check measurement: 50 tests Trouble list: 100 tests	Same
Communication System	RS-232C compliant (Switchable between one-way and two-way)	Same
Power Requirements	100 - 240 V AC (Maximum power line fluctuation of $\pm 10\%$), 50/60 Hz	Same
Power Input	Max. 150 VA	Same
Intended Use Environment	For indoor use only	Same
Measurement environment	Temperature: 10 – 30°C (50 to 86°F); Humidity: 30 – 60% RH (No condensation)	Same
Altitude	Up to 2000m (6560 feet)	Same
Differences between Proposed and Predicate Devices		
Intended Use and Indications for Use	<p>The AUTION MAX AX-4060 Urinalysis System (AUTION MAX) is comprised of the AUTION MAX AX-4060 automated urine analyzer and AUTION Sticks 9EB multi-parameter test strips.</p> <p>The AUTION MAX AX-4060 urine analyzer, when used with AUTION Sticks 9EB test strips is a fully automated urinalysis system intended for the in vitro qualitative or semi-quantitative measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes, turbidity, and color. The test results of these parameters can be used in the evaluation of kidney, urinary, liver and</p>	<p>The AUTION MAX AX-4030 Urinalysis System (AUTION MAX) is an automated urine analyzer intended for the in vitro measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes, specific gravity, turbidity, and color. The AUTION MAX is intended for use only with AUTION Sticks 9EB multi-parameter test strips.</p>

	<p>other metabolic disorders. This system is intended to be used by trained operators in clinical laboratories.</p> <p>AUTION Sticks 9EB test strips are test strips for the in vitro qualitative or semi-quantitative measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, and leukocytes with the AUTION MAX AX-4060 urine analyzer. The test results of these parameters can be used in the evaluation of kidney, urinary, liver and other metabolic disorders.</p> <p>Special conditions for use statements: Prescription use only. AUTION Sticks 9EB test strips are not to be read visually.</p>	
<p>Configuration</p>	<p>Instrument, Sampler, Hand-held barcode reader and Accessories</p>	<p>Same, but the Hand-held barcode is optional.</p>

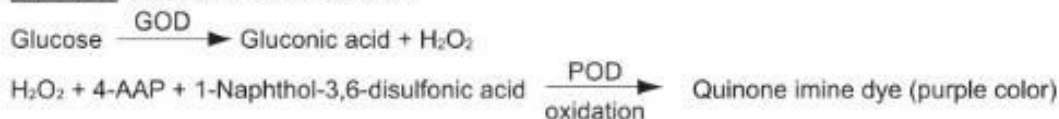
COMPONENT/ CHARACTERISTIC	PROPOSED	PREDICATE
LED Wavelength	5 LED wavelengths (450, 525, 562 , 635 and 760 nm)	5 LED wavelengths (430, 500, 565, 635, 760 nm)
Warm-up Time	Max. 4 minutes	Max. 2 minutes
Display	Large color liquid crystal display (800 × 480 dots) with touch panel	Large color liquid crystal display (320 x 240 dots) No touch panel
External Output	1 port (Replaceable with the optional Ethernet terminal)	2 ports (One of these ports can be optionally used as an Ethernet port)
Transmission Speed	RS-232C: Selectable from 300, 600, 1200, 2400, 4800, 9600 and 19200 bps Ethernet: 10BASE-T, 100BASE-TX	RS-232C: Selectable from 300, 600, 1200, 2400, 4800, 9600, and 19200 bps Ethernet: 10BASE-T
Dimensions	530 (W) × 530 (D) × 550 (H) mm (including the sampler)	530 (W) x 530 (D) x 530(H) mm (including the sampler)
Weight	Instrument: Approx. 40 kg (88 lb) Sampler: Approx. 4 kg (9 lb)	Instrument: approx. 37 kg Sampler: approx. 4 kg
Storage Environment	Temperature: -10 – 50°C (14 to 122°F); Humidity: 20 – 80% RH (No condensation)	Temperature: 1 – 30°C (34 to 86°F); Humidity: 20 – 80% RH (No condensation)
Environment during Transport	Temperature: -10 – 50°C (14 to 122°F); Humidity: 20 – 80% RH (No condensation)	Temperature: -13 – 43°C (9 to 109°F); Humidity: 20 – 80% RH (No condensation)

Test Principle:

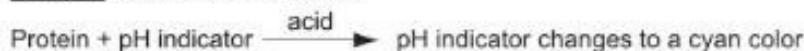
The AUTION MAX AX-4060 urine analyzer measures analyte-specific test strips (AUTION Sticks 9EB) by dual-wavelength reflectance measurement (single wavelength for blood [BLD]). The AUTION MAX AX-4060 Urinalysis System detects urine analytes based on chemical reaction on each test pad relative to the concentration of measured analytes present in the urine sample. The chemical reaction leading to the color change that occurs on each chemical test pad is listed below.

PRINCIPLE

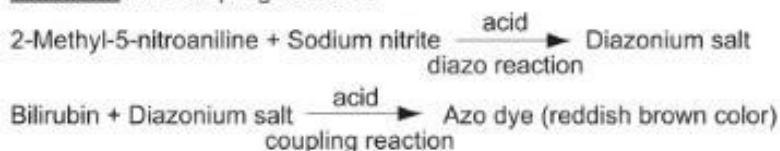
Glucose: Glucose oxidase reaction.



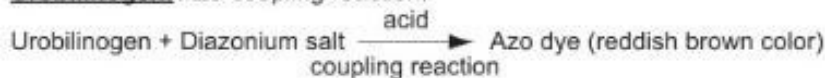
Protein: Protein-error reaction.



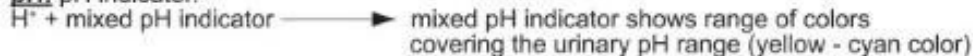
Bilirubin: Azo-coupling reaction.



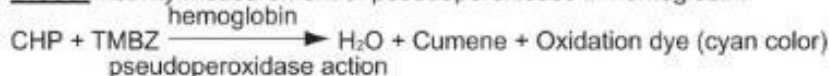
Urobilinogen: Azo-coupling reaction.



pH: pH indicator.



Blood: Activity measurement of pseudoperoxidase in hemoglobin.



Ketones: Legal reaction.



Nitrite: Griess reaction.



Leukocytes: Measurement of leukocyte esterase activity.



Performance Characteristics

Precision

Precision study included repeatability and reproducibility testing in accordance with the CLSI standard EP5-A3. 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 by mixing as needed to obtain the highest and mid-level controls for testing of all the analyte ranks. Each analyte was tested using 4 operators on 3 devices combined with 3 lots of reagents for a minimum of 20 days. Results for each level are presented in **Table 3**, **Table 4** and **Table 5**.

Table 3. Repeatability and Reproducibility of AUTION MAX AX-4060 Urinalysis System Combined results for Level 1 (Negative/Normal) samples

Results of all combinations					
		Repeatability (N=120)		Reproducibility (N=240)	
Analyte	Expected Result	Exact match	Within +/- 1 CB	Exact match	Within +/- 1 CB
GLU	Normal	100.0%	100.0%	100.0%	100.0%
PRO	Negative	100.0%	100.0%	100.0%	100.0%
BIL	Negative	100.0%	100.0%	100.0%	100.0%
URO	Normal	100.0%	100.0%	100.0%	100.0%
pH	5.0	99.2%	100.0%	99.6%	100.0%
BLD	Negative	100.0%	100.0%	100.0%	100.0%
KET	Negative	100.0%	100.0%	100.0%	100.0%
NIT	Negative	100.0%	100.0%	100.0%	100.0%
LEU	Negative	100.0%	100.0%	100.0%	100.0%
TURB	Negative	100.0%	100.0%	100.0%	100.0%
Color	Colorless	100.0%	100.0%	100.0%	100.0%

Table 4. Repeatability and Reproducibility of AUTION MAX AX-4060 Urinalysis System
Combined results for Level 2 (High) samples

			Results of all combinations			
	Expected Result		Repeatability (N=120)		Reproducibility (N=240)	
Analyte	Qualitative	Semi-quantitative (mg/dL)	Exact match	Within +/- 1 BC	Exact match	Within +/- 1 BC
GLU	+3	300-500	100.0%	100.0%	100.0%	100.0%
PRO	+3	300-600	90.8%	100.0%	94.6%	100.0%
BIL	+3	6-10	100.0%	100.0%	100.0%	100.0%
URO	+4	>12	100.0%	100.0%	95.8%	100.0%
pH	8.0	8.0	99.2%	100.0%	99.6%	100.0%
BLD	+2	0.2-0.5	100.0%	100.0%	100.0%	100.0%
KET	+3	80-100	98.3%	100.0%	99.2%	100.0%
NIT	+2		100.0%	100.0%	100.0%	100.0%
LEU		>500 (<i>Leu/μL</i>)	100.0%	100.0%	100.0%	100.0%
TURB	+2		100.0%	100.0%	100.0%	100.0%
Color	dark yellow		100.0%	100.0%	100.0%	100.0%

Table 5. Repeatability and Reproducibility of AUTION MAX AX-4060 Urinalysis System
Combined results for Level 3 (Mid) samples

			Results of all combinations			
	Expected Result		Repeatability (N=120)		Reproducibility (N=240)	
Analyte	Qualitative	Semi-quantitative (mg/dL)	Exact match	Within +/- 1 BC	Exact match	Within +/- 1 BC
GLU	+1	70-100	100.0%	100.0%	100.0%	100.0%
PRO	+1	30-70	100.0%	100.0%	100.0%	100.0%
BIL	+2	2-4	100.0%	100.0%	100.0%	100.0%
URO	+2	4-6	99.2%	100.0%	99.2%	99.6%
pH	6.5	6.5	100.0%	100.0%	100.0%	100.0%
BLD	+1	0.06-0.1	100.0%	100.0%	100.0%	100.0%
KET	+1	10-20	99.2%	99.2%	99.2%	99.6%
NIT	+1		100.0%	100.0%	100.0%	100.0%
LEU		250 (<i>Leu/μL</i>)	100.0%	100.0%	99.2%	100.0%
TURB	+1		100.0%	100.0%	100.0%	100.0%
Color	yellow		100.0%	100.0%	100.0%	100.0%

Method Comparison

A method comparison study was conducted to evaluate the agreement of results from AUTION MAX AX-4060 Urinalysis System to the FDA-cleared predicate device AUTION MAX AX-4030 Automated Urinalysis System. Testing was performed at two (2) clinical laboratories by using two (2) instruments and two (2) different lots of test strips. A total of 1374 samples, consisting of 1333 natural patient samples and 41 spiked samples, were tested across the sites.

The data from each site was combined and are presented in **Table 6** showing percentages of Exact Match and within +/- 1 Color Block Match for all analytes on test strips. Non-test strip items for turbidity and color tone are in the same templates of **Table 7** and **Table 8** as the test strip analytes.

Table 6. Overall agreement of results for all test analytes between proposed and predicate device

Analyte	All Samples (n)	Exact Match (n)	% Exact Match	95% CI	% +/- 1 CB Match
GLU	1044	1024	98.1%	97.2% - 98.8%	100.0%
PRO	1048	990	94.5%	93.0% - 95.8%	100.0%
BIL	1338	1331	99.5%	99.0% - 99.8%	100.0%
URO	1341	1330	99.2%	98.6% - 99.6%	100.0%
pH	1063	987	92.9%	91.2% - 94.3%	100.0%
BLD	1044	1000	95.8%	94.5% - 96.9%	100.0%
KET	1336	1322	99.0%	98.3% - 99.4%	100.0%
NIT	1046	1043	99.7%	99.3% - 99.9%	100.0%
LEU	1044	1029	98.6%	97.8% - 99.2%	100.0%

Table 7. Summary table for turbidity

Analyte	All Samples (n)	Exact Match (n)	% Exact Match	95% CI	% +/- 1 CB Match
Turbidity	1044	1029	98.6%	97.8%-99.2%	100%

Table 8. Summary table for color tone

Analyte	All Samples (n)	Exact Match (n)	% Exact Match	95% CI	% +/- 1 CB Match
Color tone	1044	863	82.7%	80.3% - 84.9%	100.0%

Interfering Substances

Evaluation of interfering substances influencing the accuracy of results on AUTION MAX AX-4060 Urinalysis System was conducted with AUTION Sticks 9EB.

A list of interfering substances for a given analyte is provided in **Table 9** below. The interfering substances and their highest concentrations tested with no interference are listed in **Table 10** below.

Table 9. Substances interfering with test analytes

Analyte	Substance	Concentration limit with no significant interference	Effect when above the concentration limit
Glucose	Ascorbic Acid	20 mg/dL	At 50 mg/dL decreased from +2 to +1
	Urobilinogen	4 mg/dL	At 8 mg/dL decreased from +2 to +1
	MESNA	100 mg/dL	At 150 mg/dL increased from NORMAL to +/-
Protein	Sodium Bicarbonate	200 mg/dL	At 250 mg/dL increased from +3 to +4
	Specific Gravity	1.02	At 1.025 decreased from +3 to +2
	Hemoglobin	10 mg/dL	At 12 mg/dL increased from - to +/-
Urobilinogen	Bilirubin	3.5 mg/dL	At 7 mg/dL increased from NORMAL to +1
Blood	Ascorbic Acid	50 mg/dL	At 100 mg/dL decreased from +2 to +1
	MESNA	50 mg/dL	At 100 mg/dL decreased from +2 to +1
	Urine pH	pH 8.5	At pH 9 decreased from +2 to +/-
	Methyl-dopa	50 mg/dL	At 67 mg/dL increased from - to +/-
Ketones	MESNA	1.5 mg/dL	At 3 mg/dL increased from - to +/-
Nitrite	Ascorbic Acid	50 mg/dL	At 100 mg/dL decreased from +2 to +1
	MESNA	150 mg/dL	At 200 mg/dL decreased from +2 to +1
	Urobilinogen	5 mg/dL	At 8 mg/dL decreased from +2 to +1
Leukocytes	Bilirubin	7 mg/dL	At 10.5 mg/dL increased from negative to 25
	Hemoglobin	3 mg/dL	At 6.25 mg/dL decreased from 250 to 75
	MESNA	370 mg/dL	At 660 mg/dL decreased from 250 to 75

Based on the interference testing, following limitations have been included in the labeling:

1. Elevated hematuria (6.25 mg/dL Hb, approximately 2,156 RBC/ μ L) has been shown to cause falsely lowered Leukocyte readings and should be considered when interpreting Leukocyte results.
2. Samples from patients taking methyl dopa may be falsely elevated for blood, negative to trace at 67 mg/dL and negative to +1 at 225 mg/dL. Patients taking the maximum daily dose of methyl dopa may have approximately 210 mg/dL methyl dopa excreted in the urine.
3. Patients taking SGLT2 or similar inhibitors may have extremely high urinary glucose values. Due to a hook effect on the glucose pad, if a patient's urine glucose level is greater than 20,000 mg/dL, then falsely decreased glucose results may be obtained with the test.
4. When acidic or alkaline compounds, such as ascorbic acid and sodium bicarbonate are taken internally for treatment or as supplements, they may affect urine pH.

Table 10. Substances with no interference for the highest levels tested

Interfering Substances	Highest Concentration Tested with No Interference**
Therapeutic drugs	
Acetaminophen	40 mg/dL
Acetoacetic Acid Lithium	150 mg/dL
Ammonium Chloride	400 mg/dL
Amoxicillin	360 mg/dL
Calcium Chloride	300 mg/dL
Citric Acid Monohydrate	75 mg/dL
Oxalic Acid Dihydrate	70 mg/dL
Potassium Chloride	1000 mg/dL
Sodium Chloride	2000 mg/dL
Sodium Dihydrogen Phosphate	1000 mg/dL
Sodium Nitrate	10 mg/dL
Sodium Nitrite	2 mg/dL
Endogenous substances	
Albumin	1000 mg/dL
Creatinine	600 mg/dL
Fructose	100 mg/dL
Galactose	100 mg/dL
Glucose	2000 mg/dL
Glycine	450 mg/dL
Lactose	108 mg/dL
Low Urine pH	pH 5
Riboflavin	10 mg/dL
Urea	3000 mg/dL

** Not all of the substances tested for interference demonstrated no significant interference for all analytes. For those substances that on initial screening were found to interfere with certain analytes, dose-response testing was conducted to establish the concentration limit below which no significant interference is expected. The results are given in Table 10 above.

Limits of Detection and Sensitivity

Limits of detection and Minimum detection sensitivity were determined based on three instruments, and three reagent lots. Listed below in **Table 11-14** are the quantitative values indicating the lower limit of the rank in which 50% or more of the results are falling into the specific rank.

Table 11. Minimum detection sensitivity

Analyte	Minimum detection sensitivity
GLU	30 mg/dL (+/-)
PRO	10 mg/dL (+/-)
BIL	0.5 mg/dL (+ 1)
URO	2.0 mg/dL (+ 1)
BLD	0.023 mg/dL (+/-)
KET	4.0 mg/dL (+/-)
NIT	0.075 mg/dL (+ 1)
LEU	14 Leu/ μ L

Table 12. Detection sensitivity for each Rank

	Block output	Semi-quantitative rank	Evaluation Conc.(mg/dL)	% Positive
GLU	+/-	30,50	30	100%
	+1	70, 100	60	93%
	+2	150,200	125	97%
	+3	300,500	250	100%
	+4	1000, over	750	100%
PRO	+/-	10, 20	10	67%
	+1	30, 70	30	77%
	+2	100, 200	85	53%
	+3	300, 600	250	73%
	+4	over	800	93%
BIL	+1	0.5, 1.0	0.5	53%
	+2	2.0, 4.0	1.5	93%
	+3	6.0, 10.0	5	93%
	+4	over	12	93%
URO	+1	2.0, 3.0	2	60%

	+2	4.0, 6.0	4	80%
	+3	8.0, 12.0	7	100%
	+4	over	14	100%
BLD	+/-	0.03	0.023	100%
	+1	0.06, 0.10	0.045	100%
	+2	0.20, 0.50	0.15	97%
	+3	1.00, over	0.75	73%
KET	+/-		4	97%
	+1	10, 20	7.5	100%
	+2	40, 60	30	100%
	+3	80, 100	70	63%
	+4	150, over	150	100%
NIT	+1		0.075	57%
	+2		0.3	100%

Table 13. Detection sensitivity for each Rank of pH

	Block output	Semi-quantitative rank	Evaluation pH	% Positive
pH	5.5	5.5	5.3	100%
	6	6	5.8	100%
	6.5	6.5	6.2	100%
	7	7	6.8	93%
	7.5	7.5	7.3	80%
	8	8	8	100%
	8.5	8.5	8.5	100%
	9	9	8.8	87%

Table 14. Detection sensitivity for each Rank of LEU

	Block output	Semi-quantitative rank	Evaluation Conc.	% Positive
LEU	25	25	14 cells/ μ L	100%
	75	75	48 cells/ μ L	70%
	250	250	172 cells/ μ L	60%
	500	500	396 cells/ μ L	90%

Linearity

Linearity was evaluated for Non-strip based analytical parameters. **Tables 15** and **16** below respectively show the linearity for Color tone and Turbidity.

Table 15. Linearity for Color tone

Color	Exact match
COLORLESS	100% (54/54)
BROWN	100% (54/54)
ORANGE	100% (54/54)
YELLOW	100% (54/54)
GREEN	100% (54/54)
BLUE	100% (54/54)
VIOLET	100% (54/54)
RED	100% (54/54)

Table 16. Linearity for Turbidity

Analyte	Rank	Exact match
Turbidity	-	100% (60/60)
	+1	100% (60/60)
	+2	100% (60/60)

Proposed Labeling

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

Conclusion

The information provided in this 510(k) premarket notification supports that the AUTION MAX AX-4060 Urinalysis System is substantially equivalent to the AUTION MAX AX-4030 Fully-Automated Urinalysis System.