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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

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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Shiga Japan, 520-3306

**Submitter:** ARKRAY 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<br>Control measurement: 200 tests<br>Check measurement: 50 tests<br>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 ±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 | 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.<br><br>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 | 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. |

| | | |
|---|---|---|
| | other metabolic disorders. This system is intended to be used by trained operators in clinical laboratories.<br><br>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.<br><br>Special conditions for use statements:<br>Prescription use only.<br>AUTION Sticks 9EB test strips are not to be read visually. | |
| Configuration | Instrument, Sampler, Hand-held barcode reader and Accessories | Same, but the Hand-held barcode is optional. |

| 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)<br>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<br>Ethernet: 10BASE-T, **100BASE-TX** | RS-232C: Selectable from 300, 600, 1200, 2400, 4800, 9600, and 19200 bps<br>Ethernet: 10BASE-T |
| Dimensions | 530 (W) × 530 (D) × **550 (H)** mm (including the sampler) | 530 (W) x 530 (D) x 530(H) mm<br>(including the sampler) |
| Weight | Instrument: Approx. **40 kg (88 lb)**<br>Sampler: Approx. 4 kg (9 lb) | Instrument: approx. 37 kg<br>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);<br>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.

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

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

**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.

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

**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

### 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 *(Leu/µL)* | 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 *(Leu/µL)* | 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/µL) 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/μL |

**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/ $\mu$ L | 100% |
| | 75 | 75 | 48 cells/ $\mu$ L | 70% |
| | 250 | 250 | 172 cells/ $\mu$ L | 60% |
| | 500 | 500 | 396 cells/ $\mu$ 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.