May 3, 2024

Arkray Inc.
% Daya Ranamukhaarachi
VP/Science and Regulatory Affairs
ARKRAY, Inc.
5198 West 76th Street
Minneapolis, Minnesota 55439

Re: K232416
Trade/Device Name: AUTION EYE AI-4510 Urine Particle Analysis System
Regulation Number: 21 CFR 864.5200
Regulation Name: Automated cell counter
Regulatory Class: Class II
Product Code: LKM
Dated: April 5, 2024
Received: April 5, 2024

Dear Daya Ranamukhaarachi:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Min Wu -S

Min Wu
Branch Chief
Division of Immunology and Hematology 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)*
K232416

Device Name
AUTION EYE AI-4510 Urine Particle Analysis System

Indications for Use *(Describe)*
AUTION EYE AI-4510 Urine Particle Analysis System is a fully automated urine particle analyzer for in vitro diagnostic use. AUTION EYE AI-4510 is intended for the quantitative measurement of red blood cells (RBC), white blood cells (WBC) and squamous epithelial cells (SQEC), the semi-quantitative measurement of bacteria (BACT) and crystals (CRYS) and the qualitative measurement of white blood cell clumps (WBCC), non-squamous epithelial cells (NSE), hyaline casts (HYAL), non-hyaline casts (NHC), yeast (YST), mucus (MUCS) and sperm (SPRM) in urine samples.

A trained operator can set criteria for flagging specimens. All instrument analyte image decisions should be reviewed and reclassified as necessary by a trained technologist.

The AUTION EYE AI-4510 analyzer can be used as a standalone unit or combined with an AUTION MAX AX-4060 urine chemistry analyzer.

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 EYE AI-4510 Urine Particle Analysis System is submitted in compliance with 21 CFR807.92 for the purposes of safety and effectiveness.

Date Prepared: April 03, 2024

Establishment:
ARKRAY Factory Inc.
1480 Koji, Konan-cho,
Koka-shi
Shiga Japan, 520-3306

Submitter:
ARKRAY Inc.
Yousuien-nai, 59 Gansuin-cho,
Kamigyo-ku
Kyoto Japan, 602-0008

Official US Agent:
Daya Ranamukhaarachchi, PhD
ARKRAY Factory USA Inc.
Title: VP/Science and Regulatory Affairs
Phone (408) 234-0804
Email: ranamukd@arkrayusa.com

Primary Contact:
Ryan Hanson
ARKRAY Factory USA Inc.
Title: Science Affairs Manager
Phone (952) 646-3121
Email: hansonr@arkrayusa.com

Secondary Contact:
Marissa Brooks
ARKRAY Factory USA Inc.
Title: Regulatory Affairs Project Manager
Phone (760) 525-8405
Email: brooksm@arkrayusa.com

Device Name:

Trade Name: AUTION EYE AI-4510 Urine Particle Analysis System

Common Name: Automated cell counter (Urine particle counter)

Predicate Device:

Trade Name: iQ200 Urine Analyzer (K093861)

Common Name: Automated Urinalysis System

5.1 Regulatory Information:

Regulatory Classification for Automated cell counter (Urine particle counter) and each of the tests are listed in **Table 1**.

Table 1. Regulatory Classification for the AI-4510 System

Test Description	Product Code	Device Class	Regulation	Device Panel
Urine Particle Counter	LKM	Class II	21 CFR 864.5200	81- Hematology
Automated Urinalysis System	KQO	Class I	21 CFR 862.2900	75- Chemistry

5.2 Intended Use

AUTION EYE AI-4510 Urine Particle Analysis System is a fully automated urine particle analyzer for *in vitro* diagnostic use. AUTION EYE AI-4510 is intended for the quantitative measurement of red blood cells (RBC), white blood cells (WBC) and squamous epithelial cells (SQEC), the semi-quantitative measurement of bacteria (BACT) and crystals (CRYS) and the qualitative measurement of white blood cell clumps (WBCC), non-squamous epithelial cells (NSE), hyaline casts (HYAL), non-hyaline casts (NHC), yeast (YST), mucus (MUCS) and sperm (SPRM) in urine samples.

A trained operator can set criteria for flagging specimens. All instrument analyte image decisions should be reviewed and reclassified as necessary by a trained technologist.

The AUTION EYE AI-4510 analyzer can be used as a standalone unit or combined with an AUTION MAX AX-4060 urine chemistry analyzer.

5.3 Device Description

The AI-4510 System (AUTION EYE AI-4510) is a fully automated urine particle analyzer for *in vitro* diagnostic use that uses flow cell digital imaging technology in a clinical laboratory setting. Based on images captured in the flow method, the instrument automatically classifies the images of various formed elements. The AI-4510 System can

quantitatively measure RBC, WBC, and SQEC; semi-quantitatively measure BACT, and CRYS; and qualitatively measure WBCC, NSE, HYAL, NHC, YST, MUCS and SPRM in urine samples. In addition, the AI-4510 System allows trained operators to manually review and reclassify all the element images collected by the system.

5.4 Substantial Equivalence

The following **Table 2** shows the comparisons between the predicate and candidate devices and identifies the major technological and performance characteristics.

Table 2. Comparison Between AUTION EYE AI-4510 and iQ200 SYSTEM

COMPONENT/ CHARACTERISTIC	PROPOSED	PREDICATE
510(K) Number	K232416	K093861
Device	AUTION EYE AI-4510 Urine Particle Analysis System	iQ200 System with Lamina Cradle
Device Type	Automated Cell Counter	Automated Cell Counter
FDA Product Code	LKM, KQO	LKM, KQO
FDA Authorization Use	Laboratory Use	Laboratory Use
Intended Use and Indication for Use	AUTION EYE AI-4510 Urine Particle Analysis System is a fully automated urine particle analyzer for *in vitro* diagnostic use. AUTION EYE AI-4510 is intended for the quantitative measurement of red blood cells (RBC), white blood cells (WBC) and squamous epithelial cells (SQEC), the semi-quantitative measurement of bacteria (BACT) and crystals (CRYS) and the qualitative measurement of white blood cell clumps (WBCC), non-squamous epithelial cells (NSE), hyaline casts (HYAL), non-hyaline casts (NHC), yeast	The iQ®200 System is an in-vitro diagnostic device used to automate the complete urinalysis profile, including urine test strip chemistry panel and microscopic sediment analysis.

	(YST), mucus (MUCS) and sperm (SPRM) in urine samples. A trained operator can set criteria for flagging specimens. All instrument analyte image decisions should be reviewed and reclassified as necessary by a trained technologist. The AUTION EYE AI-4510 analyzer can be used as a standalone unit or combined with an AUTION MAX AX-4060 urine chemistry analyzer.	Optionally, the iQ200 analyzer can be used as a stand-alone unit, or the results from the iQ200 analyzer can be combined with other urine chemistry results received from an LIS. It produces quantitative or qualitative counts of all formed sediment elements present in urine, including cells, casts, crystals, and organisms. A competent human operator can set criteria for auto-reporting and flagging specimens for review. All instrument analyte image decisions may be reviewed and overridden by a trained technologist.
Measurement Principle	Same as predicate	Flow digital imaging
Parameters	Red blood cells (RBC), White blood cells (WBC), White blood cell clumps (WBCC), Squamous epithelial cells (SQEC), Non-squamous epithelial cells (NSE), Hyaline casts (HYAL), non-hyaline casts (NHC), Bacteria (BACT), Crystals (CRYS), Yeast (YST), Mucus (MUCS) and Sperm (SPRM)	Red blood cells (RBC), White blood cells (WBC), White blood cell clumps (WBCC), Squamous epithelial cells (SQEC), Non-squamous epithelial cells (NSE), Hyaline casts (HYAL), Unclassified casts (NHC or UNCC), Bacteria (BACT), Crystals (CRYS), Yeast (YST), Mucous (MUCS), Sperm (SPRM), Dysmorphic RBC and Unclassified Crystals
Automatic Classification	Red blood cells (RBC), white blood cells (WBC), white blood cell clumps (WBCC), squamous epithelial cells (SQEC), non-squamous epithelial cells (NSE), hyaline casts (HYAL), non-hyaline casts (NHC), bacteria (BACT), crystal (CRYS), yeast (YST), mucus (MUCS) and sperm (SPRM)	Red Blood Cells (RBC), White Blood Cells (WBC), White Blood Cell Clumps (WBCC), Squamous Epithelial Cells (SQEC), Non

	(While a dysmorphic red blood cell is counted as a red blood cell, the flag can be automatically assigned for the dysmorphic red blood cell.)	Squamous Epithelial Cells (NSE), Bacteria (BACT), Crystals (UNCX), Hyaline Cast (HYAL), Unclassified Cast (UNCC), Yeast (BYST/HYST), Sperm (SPRM), Mucus (MUCS)
Manual Classification	Red blood cells: 2 items Dysmorphic red blood cells (DRBC) and red blood cell clumps (RBCC) Crystal: 10 items Calcium oxalate crystal (CAOX), calcium phosphate crystal (CAPH), magnesium ammonium phosphate crystal (TPO4), leucine crystal (LEUC), uric acid crystal (URIC), calcium carbonate crystal (CACB), cystine crystal (CYST), tyrosine crystal (TYRO), amorphous salts (phosphoric acid, uric acid) (AMOR) and unclassified crystal (UNCX) Casts: 6 items Granular casts (GRAN), waxy casts (WAXY), RBC casts (RBCT), WBC casts (WBCT), epithelial casts (EPIC) and fatty casts (FATC) Yeast: 1 item Budding yeast (BYST)	Red blood cells: 2 items Dysmorphic red blood cells (DRBC) and red blood cell clumps (RBCC) Crystal: 10 items Calcium oxalate crystal (CAOX), calcium phosphate crystal (CAPH), magnesium ammonium phosphate crystal (TPO4), leucine crystal (LEUC), uric acid crystal (URIC), calcium carbonate crystal (CACB), cystine crystal (CYST), tyrosine crystal (TYRO), amorphous salts (phosphoric acid, uric acid) (AMOR) and unclassified crystal (UNCX) Casts: 6 items Granular casts (GRAN), waxy casts (WAXY), RBC casts (RBCT), WBC casts (WBCT), epithelial casts (EPIC) and fatty casts (FATC) Yeast: 1 item Budding yeast (BYST)

	Epithelial cells: 2 items Renal tubular epithelial cells (REEP), transitional epithelial cells (TREP) Fat: 2 items Fat (FAT) and oval fat body (OVFB) Other categories: 5 items Trichomonas (TRCH), inclusion cells (INCC), parasite (PARA), artifact (ART) and unclassified (UNCL)	Epithelial cells: 2 items Renal tubular epithelial cells (REEP), transitional epithelial cells (TREP) Fat: 2 items Fat (FAT) and oval fat body (OVFB) Other categories: 5 items Trichomonas (TRCH), inclusion cells (INCC), parasite (PARA), artifact (ART) and unclassified (UNCL)
Specimen Type / Measurement Object	Urine	Urine
Reagents	AUTION EYE Sheath Solution Concentrated Washing Solution 3 AUTION EYE Calibrator	iQ Lamina Iris Diluent Iris System Cleanser iQ Focus Solution
Quality Control Solution	AUTION EYE Control Solution (It consists of High and Low levels.)	iQ Positive control, iQ Negative control
Sample Consumption Volume	Maximum 1 mL	Approximately 1.3 mL
Required Volume	2 mL or more	Minimum volume 3 mL
Measurement Time	Approximately 45 seconds/test (Excluding cases in which large numbers of formed elements are present or in the case of control measurement)	101 seconds/test

Warm up time	Maximum 10 minutes (Duration after the power is turned ON. The warm- up time is extended if a readjustment process is added during startup.)	The iQ200 System should be allowed to warm up for 1 or 2 hours if it was turned off for more than 6 hours.
Memory Capacity	Measurement results (Normal): 10,000 tests	Onboard storage of up to 10,000 patient results
Number of Captured Images	Three digital cameras capture 1,500 frames per sample	A digital camera captures 500 frames per sample
Capturing Images	Takes images with 3 different focal points using 3 digital cameras	Presents a specimen to a microscope coupled to a 1.3-megapixel CCD (charge coupling device) digital camera
Power	100 - 240 V AC, 50/60 Hz (Including fluctuations of ±10%)	Microscopy module – 90-240 VAC 50-60 Hz 200 watts max
Intended Use Environment	Indoor use only	Indoor use only
Measurement Environment	Temperature: 59 to 86 °F, Humidity: 20 to 80% (No condensation)	Temperature: 15-30°C (59-86°F) Humidity: 20% - 80% non-condensing
Measurement light source	Strobe lamp	Strobe lamp
Dimensions	530 (W) × 600 (D) × 650 (H) mm (including the sampler) 530 (W) × 200 (D) × 135 (H) mm (sampler only)	Microscopy module - 56 H x 59 W x 64.8 D cm (22 H x 23 W x 25.5 D in.)

Weight	Analyzer (with the sampler): Approx. 57 kg Sampler: Approx. 4 kg	Microscopy module - 45.4 kg (100 lbs.)

5.5 Test Principle and Technology

The principle of operation of the AI-4510 System is based on image capture and the digital processing of images for particle analysis and recognition from a locked sorting algorithm for clustering and classification.

The instrument uses flow digital imaging technology with a flow cell and Complementary Metal- Oxide- Semiconductor (CMOS) image sensors. As the urine passes through the flow cell, it is illuminated by a strobe lamp. Color images are recorded from three different focal points by the CMOS image sensors. The software processes the recorded images, automatically identifying and classifying the formed elements based on the sorting algorithm. The images and the classification of the formed elements are also displayed on the device screen for the operator. The results of the measurements of formed elements for each sample can be centrally controlled by the computer. Images that could not be classified automatically can be classified manually.

5.6 Summary of Performance Data

Clinical and bench testing were conducted to verify the performance characteristics of this device. This testing showed acceptable device performance that is substantially equivalent to the performance of the predicate device.

Precision

Precision for the AI-4510 System was evaluated to estimate repeatability, within-laboratory precision, and reproducibility for quantitative analytes: Red Blood Cell (RBC), White Blood Cell (WBC), and Squamous Epithelial Cells (SQEC), and repeatability for all semi-quantitative and qualitative elements: Bacteria (BACT), Crystals (CRYS), White blood cell clumps (WBCC), Non-squamous epithelial cells (NSE), Hyaline casts (HYAL), non-hyaline casts (NHC), Yeast (YST), Mucus (MUCS) and Sperm (SPRM).

Precision studies were conducted in accordance with the general guidelines established in *CLSI EP05*-A3; (Third Edition)- *Evaluation of Precision Devices; Approved Guideline*

Precision studies were conducted to evaluate measurement imprecision using both controlled materials and clinical samples, with all results meeting the predefined acceptance criteria.

There were three major studies conducted to demonstrate the precision of the AI-4510 System:

Repeatability Study- (Quantitative, Semiquantitative, and Qualitative Elements) Results were collected with one (1) instrument, at one (1) site, with one (1) operator and 10 replicates, using clinical urine samples in the evaluation of repeatability for all twelve (12) elements from low to high concentrations.

Within-Laboratory Precision Study- (Quantitative Elements) Results collected over twenty (20) days with two (2) runs per day and two (2) replicates per run using ARKRAY control materials prepared using clinical samples.

Reproducibility Study- (Quantitative Elements) Results collected from three (3) sites, with one (1) analyzer per site, and testing conducted over five (5) days with two (2) runs per day and three (3) replicates per run using commercially available control materials and ARKRAY control materials prepared using clinical samples.

Results from the analysis conducted for each study is presented in **Tables 3-6** below.

Table 3. Repeatability Results – Quantitative Elements

Element	Test Level	Mean Value (/μL)	Repeatability	
			SD	%CV
RBC	Low	7.5	1.2	16.2
	MDL	42.1	3.2	7.7
	Mid	468.8	16.6	3.5
	High	858.7	30.6	3.6
WBC	Low	7.8	1.3	17.2
	MDL	38.5	4.8	12.5
	Mid	425.2	7.8	1.8
	High	918.7	17.5	1.9
SQEC	Low	6.1	0.9	14.7
	MDL	39.6	3.7	9.4
	Mid	91.6	4.4	4.8
	High	161.5	6.9	4.3

Table 4. Repeatability Results – Semi-Quantitative and Qualitative Elements

Element	n	Test Level	Avg. Conc. (/μL)	% Agreement with expected rank
BACT	10	Level 1	0.0	100.0%
	10	Level 2	55.7	100.0%
	10	Level 3	78.9	100.0%
	10	Level 4	166.5	100.0%
CRYS	10	Level 1	0.0	100.0%
	10	Level 2	41.7	100.0%
	10	Level 3	118.1	100.0%
	10	Level 4	200.7	100.0%
	10	Level 5	330.1	100.0%

Element	n	Test Level	Avg. Conc. (/µL)	% Agreement with expected rank
NSE	10	Negative	0.0	100.0%
	10	Low positive	4.8	80.0%
	10	High Positive	15.5	100.0%
HYAL	10	Negative	0.0	100.0%
	10	Low positive	1.2	100.0%
	10	High Positive	8.2	100.0%
NHC	10	Negative	0.0	100.0%
	10	Low positive	1.2	100.0%
	10	High Positive	12.9	100.0%
WBCC	10	Negative	0.0	100.0%
	10	Low positive	3.3	100.0%
	10	High Positive	15.5	100.0%
YST	10	Negative	0.0	100.0%
	10	Low positive	11.4	70.0%
	10	High Positive	49.3	100.0%
MUCS	10	Negative	0.1	100.0%
	10	Low positive	32.8	100.0%
	10	High Positive	106.2	100.0%
SPRM	10	Negative	0.0	100.0%
	10	Low positive	7.4	100.0%
	10	High Positive	32.2	100.0%

Table 5. Within-Laboratory Precision Results

Level	Mean Value (/µL)	Repeatability		Between Run		Between Day		Within Laboratory	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
RBC Low	8.1	2.0	24.7	0.3	3.7	0.2	2.3	2.0	25.1
RBC MDL	43.1	4.2	9.8	2.9	6.7	0.0	0.0	5.1	11.9
RBC High	515.7	22.8	4.4	18.4	3.6	13.2	2.6	32.2	6.2
WBC Low	7.9	1.7	21.9	1.2	14.8	0.0	0.0	2.1	26.4
WBC MDL	42.9	3.4	7.9	4.0	9.3	1.5	3.5	5.5	12.7
WBC High	470.1	13.4	2.8	23.8	5.1	10.6	2.3	29.3	6.2
SQEC Low	8.6	1.4	16.1	0.0	0.0	0.5	5.7	1.5	17.0
SQEC MDL	39.5	3.1	7.9	0.7	1.7	1.1	2.7	3.4	8.5
SQEC High	158.0	6.3	4.0	2.0	1.3	2.2	1.4	7.0	4.4

Table 6. All Sites Combined – Reproducibility Study Results

Level	Mean Value (cells/µL)	Repeatability		Between Run		Between Day		Between Site		Reproducibility	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
RBC Low	8.4	2.0	23.4	0.0	0.0	0.7	8.0	0.5	6.2	2.1	25.5
RBC Mid	86.2	6.6	7.6	1.5	1.7	0.9	1.1	6.5	7.5	9.4	10.9
RBC High	675.7	53.9	8.0	0.0	0.0	13.4	2.0	64.3	9.5	85.0	12.6
WBC Low	5.7	1.4	24.5	0.5	8.2	0.3	4.8	0.2	3.2	1.5	26.5
WBC Mid	86.8	6.4	7.4	2.8	3.2	1.7	2.0	1.9	2.2	7.4	8.6
WBC High	645.0	20.9	3.2	20.4	3.2	13.8	2.1	37.6	5.8	49.6	7.7
SQEC Low	14.9	2.1	14.4	0.0	0.0	0.3	2.0	0.6	4.2	2.3	15.1
SQEC High	87.2	6.5	7.4	2.8	3.2	0.0	0.0	7.6	8.7	10.3	11.9

Linearity

Linearity testing was performed for the AI-4510 System using one instrument to establish the linear interval for quantitative elements: RBC, WBC, and SQEC. The study was conducted following *CLSI EP06-2nd Edition* and met the predefined acceptance criteria, establishing the linearity interval of the AI-4510 System quantitative elements as shown in **Table 7** below.

Table 7. AI-4510 System Linearity Interval

Quantitative Element	Linear Range
RBC	5-1,000 RBC/µL
WBC	5-1,000 WBC/µL
SQEC	5-180 SQEC/µL

Limit of Detection

Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) were conducted for the AI-4510 System quantitative (RBC, WBC, SQEC) and semiquantitative (CRYS, BACT) elements following *CLSI-EP17-A2 Evaluation of Detection Capability For Clinical Laboratory Measurement Procedures; Approved Guideline* -Second Edition. Based on the results of the study, as shown below in **Table 8**, all elements met the predefined acceptance criteria, thereby establishing the LoB, LoD, and LoQ for each element.

Table 8. Results of Detection Limits

Element(cells/µL)	LoB	LoD	LoQ
RBC	0.0	2.3	2.3
WBC	0.0	1.5	1.5
SQEC	0.2	1.6	1.6

Element(cells/µL)	LoB	LoD	LoQ
CRYS	0.0	6.4	6.4
BACT	0.0	6.0	6.0

Carryover

Carryover testing was performed for the AI-4510 System to confirm that there are no carryover contaminations for all twelve (12) elements. This testing was conducted using pre-prepared concentrations of high-level and low-level samples which were aliquoted into 5 tubes each and measured alternatively as shown in **Table 9** for each tested element. Based on the predefined acceptance criteria, no carryover effect was detected.

Table 9. Carryover Measurement Order

Measurement sequence	Sample placement in rack
Set 1	H1 L1 H2 L2 H3 L3 H4 L4 H5 L5
Set 2	H1 L1 H2 L2 H3 L3 H4 L4 H5 L5
Set 3	H1 L1 H2 L2 H3 L3 H4 L4 H5 L5
Set 4	H1 L1 H2 L2 H3 L3 H4 L4 H5 L5
Set 5	H1 L1 H2 L2 H3 L3 H4 L4 H5 L5

H: High level sample, L: Low level sample

Interference

Interference testing was performed on the AI-4510 System to evaluate the influence of interfering substances on the measurement of twelve (12) particle elements using the AI-4510 System. A dose dependency evaluation was performed for those substances which were confirmed to have interference effects on the measurements to determine the highest concentration at which no interference effect is observed.

The results of this interference study are summarized in **Tables 10-12** below.

Table 10. Interference Effect on Manually Reviewed and Reclassified Results

Element	Interferent	Concentration Limit with No Significant Interference	Concentration of Interferent and Observed Effect
RBC	Trichomonas	50 /µL	At 120 /µL falsely increased for negative samples
	Turbidity	1+ **	At 2+ falsely decreased for positive samples
	Bacteria	4000 /µL	At 6000 /µL falsely decreased for positive samples
WBC	Yeast	60 /µL	At 80 /µL falsely increased for negative samples and low positive samples
	Trichomonas	- *	At 10 /µL falsely increased for negative samples At 50 /µL falsely increased for positive samples
	Red Blood Cells	1500 /µL	At 5000 /µL falsely increased for positive samples

	Turbidity	1+ **	At 2+ falsely decreased for low positive samples
	Bacteria	7500 /µL	At 15000 /µL falsely decreased for low positive samples
WBCC	Trichomonas	50 /µL	At 120 /µL falsely increased for negative samples
SQEC	Red Blood Cells	1200 /µL	At 1500 /µL falsely decreased for positive samples
	Turbidity	1+ **	At 2+ falsely decreased for positive samples
	Bacteria	7500 /µL	At 15000 /µL falsely decreased for positive samples
BACT	Amorphous Urates	120 /µL	At 160 /µL falsely increased for low positive samples At 200 /µL falsely increased for negative samples and high positive samples
	Turbidity	1+ **	At 2+ falsely increased for low positive samples
	Yeast	60 /µL	At 80 /µL falsely increased for low positive samples
MUCS	Red Blood Cells	1500 /µL	At 5000 /µL falsely increased for high positive samples
	Bacteria	6000 /µL	At 7500 /µL falsely decreased for high positive samples
SPRM	Bacteria	6000 /µL	At 7500 /µL falsely decreased for high positive samples

* Concentration limit with no significant interference was not evaluated

** The qualitative rank as measured by an AUTION MAX AX-4060 Urine Chemistry Analyze

Table 11. Interference Effect on Auto-classified Results

Interference effect on Auto-classified results			
Element	**Interferent**	**Concentration limit with no significant interference**	**Concentration of Interferent and observed effect**
RBC	Yeast	40 /uL	At 60/uL falsely increased for negative samples At 80/uL falsely increased for low positive samples
	Crystal	- *	At 330/uL falsely increased for negative samples
	Trichomonas	50 /uL	At 120/uL falsely increased for negative samples
	Turbidity	1^+ **	At 2^+ falsely decreased for positive samples
	Bacteria	4000/uL	At 6000/uL falsely decreased for positive samples
WBC	Red blood cells	400 /uL	At 800/uL falsely increased for negative samples At 1200/uL falsely increased for low positive samples At 1500/uL falsely increased for high positive samples
	Yeast	40 /uL	At 60/uL falsely increased for negative samples At 80/uL falsely increased for low positive samples
	Trichomonas	- *	At 10/uL falsely increased for negative samples and positive samples
	Turbidity	1^+ **	At 2^+ falsely decreased for low positive samples
	Bacteria	7500 /uL	At 15000 /uL falsely decreased for low positive samples
WBCC	Red blood cells	1200 /uL	At 5000 /uL falsely increased for negative samples

	Yeast	60 /uL	At 80 /uL falsely increased for negative samples
	Trichomonas	20 /uL	At 50 /uL falsely increased for negative samples
SQEC	Red blood cells	1200 /uL	At 1500/uL falsely decreased for positive samples
	Turbidity	1^+ **	At 2^+ falsely decreased for positive samples
	Bacteria	7500 /uL	At 15000 /uL falsely decreased for positive samples
NHC	Yeast	60 /uL	At 80 /uL falsely increased for negative samples and low positive samples
BACT	Amorphous urates	120 /uL	At 200 /uL falsely increased for negative samples and high positive samples At 160 /uL falsely increased for low positive samples
	Yeast	60 /uL	At 80 /uL falsely increased for low positive samples
	Turbidity	1^+ **	At 2^+ falsely decreased for low positive samples
YST	Red blood cells	1200 /uL	At 5000 /uL falsely increased for negative samples and low positive samples
MUCS	Red blood cells	1500 /uL	At 5000 /uL falsely decreased for high positive samples
	Bacteria	6000 /uL	At 7500 /uL falsely decreased for high positive samples
SPRM	Bacteria	6000 /uL	At 7500 /uL falsely decreased for high positive samples

* Concentration limit with no significant interference not evaluated.

** The qualitative rank as measured by an AUTION MAX AX-4060 urine chemistry analyzer

Table 12. Elements for which No Interference was Observed

Element	Interfering Substances	Highest Concentration Tested with No Interference
RBC	Viscosity	1.24 mPa・s
	MUCS	200 /μL
	Amorphous Urates	320 /μL
	Calcium Oxalate Crystal	330 /μL
	Yeast	100 /μL
WBC	Viscosity	1.24 mPa・s
	MUCS	200 /μL
	Amorphous Urates	320 /μL
	Calcium Oxalate Crystal	330 /μL
WBCC	Turbidity	2+
	Viscosity	1.24 mPa・s
	Red Blood Cells	5000 /μL
	MUCS	200 /μL
	Amorphous Urates	320 /μL
	Calcium Oxalate Crystal	330 /μL
	Bacteria	15000 /μL
	Yeast	100 /μL
SQEC	Viscosity	1.24 mPa・s
	Trichomonas	120 /μL
	MUCS	200 /μL
	Amorphous Urates	320 /μL

	Calcium Oxalate Crystal	330 /μL
	Yeast	100 /μL
NSE	Turbidity	2+
	Viscosity	1.24 mPa・s
	Trichomonas	120 /μL
	Red Blood Cells	5000 /μL
	MUCS	200 /μL
	Amorphous Urates	320 /μL
	Calcium Oxalate Crystal	330 /μL
	Bacteria	15000 /μL
	Yeast	100 /μL
HYAL	Turbidity	2+
	Viscosity	1.24 mPa・s
	Trichomonas	120 /μL
	Red Blood Cells	5000 /μL
	MUCS	200 /μL
	Amorphous Urates	320 /μL
	Calcium Oxalate Crystal	330 /μL
	Bacteria	15000 /μL
	Yeast	100 /μL
NHC	Turbidity	2+
	Viscosity	1.24 mPa・s
	Trichomonas	120 /μL
	Red Blood Cells	5000 /μL
	MUCS	200 /μL
	Amorphous Urates	320 /μL
	Calcium Oxalate Crystal	330 /μL
	Bacteria	15000 /μL
	Yeast	100 /μL
BACT	Viscosity	1.24 mPa・s
	Trichomonas	120 /μL
	Red Blood Cells	5000 /μL
	MUCS	200 /μL
	Calcium Oxalate Crystal	330 /μL
CRYS	Turbidity	2+
	Viscosity	1.24 mPa・s
	Trichomonas	120 /μL
	Red Blood Cells	5000 /μL
	MUCS	200 /μL
	Amorphous Urates	320 /μL
	Bacteria	15000 /μL
	Yeast	100 /μL
YST	Turbidity	2+
	Viscosity	1.24 mPa・s
	Trichomonas	120 /μL
	Red Blood Cells	5000 /μL

	MUCS	200 /μL
	Amorphous Urates	320 /μL
	Calcium Oxalate Crystal	330 /μL
	Bacteria	15000 /μL
MUCS	Turbidity	2+
	Viscosity	1.24 mPa・s
	Trichomonas	120 /μL
	Amorphous Urates	320 /μL
	Calcium Oxalate Crystal	330 /μL
	Yeast	100 /μL
SPRM	Turbidity	2+
	Viscosity	1.24 mPa・s
	Trichomonas	120 /μL
	Red Blood Cells	5000 /μL
	MUCS	200 /μL
	Amorphous Urates	320 /μL
	Calcium Oxalate Crystal	330 /μL
	Yeast	100 /μL

Sample Stability

Sample stability was evaluated on the AI-4510 System to confirm the sample stability of twelve (12) elements when measured with the AI-4510 System. Testing was performed on both positive and negative samples for all twelve (12) elements at room temperature (15-30°C) and under refrigeration (2-8°C). In conclusion, all samples tested for each element met the predefined acceptance criteria, therefore establishing the sample stability at room temperature (15-30°C) for up to 2 hours and under refrigeration (2-8°C) for up to 6 hours for all twelve (12) elements measured by the AI-4510 System.

Method Comparison

A method comparison study was conducted at three (3) CLIA-Moderate complexity laboratories to evaluate the agreement of urine sample test results between the candidate device, the AI-4510 System, and the FDA-cleared predicate device, the iQ200 System (K093861) and manual microscopy. Testing was done by CLIA-trained operators using de-identified urine samples collected fresh within two (2) hours or refrigerated up to six (6) hours post collection. The study was conducted to evaluate the following 12 analytes: Quantitative analysis of red blood cells (RBC), white blood cells (WBC), and squamous epithelial cells (SQEC); Semiquantitative analysis of bacteria (BACT), and crystals (CRYS); Qualitative analysis of hyaline casts (HYAL), non-hyaline casts (NHC), non-squamous epithelial cells (NSE), yeast (YST), white blood cell clumps (WBCC), mucus (MUCS) and sperm (SPRM). **Tables 13-16** summarize the reference range analysis as well as the overall clinical performance data for all sites combined. In summary, Quantitative, Semiquantitative and Qualitative parameters met the acceptance criteria.

Table 13. Reference Range results (n=247)

Element	***95% Reference Limit***	***90% CI***
RBC	9.02	7.34 – 10.70
WBC	4.81	3.80 – 5.50
SQEC	6.46	4.50 – 9.30
NSE	3.21	2.50 - 4.54
NHC	0.11	0.00 - 0.30
HYAL	0.51	0.26 - 0.82
BACT	119.6	66.28 - 180.66
CRYS	0.03	0.00 - 0.00
YST	0	0.00 - 0.00
WBCC	0.05	0.00 - 0.30
MUCS	26.6	20.50 - 35.39
SPRM	0	0.00 - 0.00

Table 14. Method Comparison Results for Quantitative Elements

Weighted Deming Regression					
Element	*Comparison*	*N*	*R^2*	*Intercept*	*Slope*
RBC	AI(M) vs. IQ(M)	377	**0.918**	**1.501** (0.432, 2.569)	**0.824** (0.763, 0.886)
WBC	AI(M) vs. IQ(M)	845	**0.903**	**0.629** (-0.300. 1.558)	**0.968** (0.930, 1.006)
SQEC	AI(M) vs. IQ(M)	382	**0.928**	**-0.451** (-1.269, 0.367)	**0.933** (0.883, 0.982)

* (M) denotes manually reviewed and reclassified results.

Passing-Bablok Regression					
Element	*Comparison*	*N*	*R^2*	*Intercept*	*Slope*
RBC	AI(M) vs. IQ(M)	377	**0.918**	**0.332** (-0.500, 1.490)	**0.824** (0.774, 0.886)
WBC	AI(M) vs. IQ(M)	845	**0.903**	**1.992** (1.140, 3.067)	**0.891** (0.860, 0.925)
SQEC	AI(M) vs. IQ(M)	382	**0.928**	**0.641** (-0.066, 1.493)	**0.873** (0.826, 0.923)

* (M) denotes manually reviewed and reclassified results.

Table 15. Method Comparison results for Semi-quantitative elements

BACT

AI-4510 (Manual) vs. Manual Microscopy	
N	1474
Sensitivity	76.2% (72.9%, 79.3%)
Specificity	83.7% (81.0%, 86.1%)

CRYS

AI-4510 (Manual) vs. Manual Microscopy	
N	1474
PPA	90.5% (85.1%, 94.1%)
NPA	98.2% (97.3%, 98.8%)

Table 16. Method Comparison results for Qualitative elements

NSE

AI-4510 (Manual) vs. iQ200 (Manual)	
N	765
PPA	88.7% (77.4%, 94.7%)
NPA	84.3% (81.4%, 86.8%)

NHC

AI-4510 (Manual) vs. iQ200 (Manual)	
N	765
PPA	80.2% (71.6%, 86.7%)
NPA	83.8% (80.8%, 86.4%)

HYAL

AI-4510 (Manual) vs. iQ200 (Manual)	
N	765
PPA	85.0% (78.4%, 89.9%)
NPA	89.0% (86.3%, 91.2%)

YST

AI-4510 (Manual) vs. iQ200 (Manual)	
N	765
PPA	97.1% (85.1%, 99.5%)
NPA	99.6% (98.8%, 99.9%)

WBCC

AI-4510 (Manual) vs. iQ200 (Manual)	
N	1474
PPA	86.5% (80.5%, 90.8%)
NPA	89.3% (87.5%, 90.8%)

MUCS

AI-4510 (Manual) vs. iQ200 (Manual)	
N	1474
PPA	81.9% (76.3%, 86.5%)
NPA	88.0% (86.1%, 89.7%)

SPRM

AI-4510 (Manual) vs. iQ200 (Manual)	
N	1474
PPA	86.2% (75.1%, 92.8%)
NPA	99.6% (99.2%, 99.8%)

5.7 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.

5.8 Conclusion

ARKRAY has demonstrated the AI-4510 System is substantially equivalent to the predicate device, the iQ200 System, based upon design, test results, and indications for use. Any noted differences do not raise new issues of safety and effectiveness.