510(k) SUBSTANTIAL EQUIVALENCE DETERMINATIONS
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

K182062

B. Purpose for Submission:

Clearance of a new device

C. Manufacturer and Instrument Name:

Sysmex America, Inc., Sysmex® UD-10 Fully Automated Urine Particle Digital Imaging Device

D. Type of Test or Tests Performed:

The Sysmex UD-10 locates urine particles, measures the size of the particle, and sorts the particles by size into eight groups (Class 1–8).

E. System Descriptions:

1. Device Description:

   The Sysmex UD-10 is a urine cell particle locating device that consists of the following components which perform the following functions:

   - Main analyzer: for sample aspiration, cell particle imaging, touch panel for operator interfacing with the system
   - Sampler Section CV-11: to automatically transport samples to the main analyzer
   - Data Processor (IPU): to process data received from the analyzer
   - Pneumatic unit; to regulate the pressure supplied to the analyzer
   - Urinalysis Data Manager (UDM) Software: to allow the operator to monitor and manage data generated on the Sysmex UD-10, enter and manage patient information and results, validate imaging results, check quality control results, connect to a host computer. The UDM Software does not modify the data generated by the Sysmex UD-10 nor does it control the Sysmex UD-10 analyzer.
   - Software of UD-10: for analyzer operation and to store/review data
   - Accessories: sample rack set, hand-held barcode reader, and power cord

2. Principles of Operation:

   The Sysmex UD-10 aspirates uncentrifuged urine samples using an aspiration pipette and introduces the sample to an imaging cell. The sample is allowed to sit for a specified

duration of time, during which particles settle to the bottom of the imaging cell. The LED emits pulses of light as the imaging cell is moved, and images are captured with the camera. The captured image is analyzed on the IPU (information processing unit) and the particles in the image are displayed by size into one of the following eight groups. The number of particles per size group does not represent a reportable cell or particle count.

Size Group	Size Range (µm)
Class 1	2–6
Class 2	6–10
Class 3	10–16
Class 4	16–36
Class 5	36–71
Class 6	71–101
Class 7	101–151
Class 8	≥151

The displayed data consists of images of individual particles extracted from the original captured whole field images. The images are transferred to the UDM where the operator manually enters the classification of the particle images based on their visual examination, where the classified particle is reported as present or absent. The classification of the particles by the operator is a designation of type of particles observed (e.g., WBCs, RBCs, casts, bacteria).

3. Modes of Operation:

   Automated Sampling Mode

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes __X___ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No __X__

4. Specimen Identification:

   Hand-held barcode reader

5. Specimen Sampling and Handling:

   Uncentrifuged urine specimens are introduced to the Sysmex UD-10 by automated aspiration by the aspiration pipette.

6. Calibration:

   There are no user calibration requirements for the Sysmex UD-10 device. Particle size is by factory setting and there is no user calibration required.

7. Quality Control:

   The Sysmex UD-10 is intended to be used with the low and high UF-CONTROL reagents to monitor the performance of the analyzer. The controls are used to verify proper functioning of the system hardware, including the imaging cell preparation process and cell location performance.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes ____X___ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 864.5260, Automated cell-locating device

2. Classification:

   Class II

3 Product code:

   JOY, Device, Automated cell-locating

4. Panel:

   Hematology (81)

G. Intended Use:

1. Indication for Use:

   The Sysmex UD-10 is a Fully Automated Urine Particle Digital Imaging Device for locating, digitally storing and displaying microscopic images captured from urine specimens. The Sysmex UD-10 locates and presents particles and cellular elements based on size ranges. The images are displayed for review and classification by a qualified clinical laboratory technologist on the Urinalysis Data Manager (UDM). This

device is intended for in vitro diagnostic use in conjunction with a urine particle counter for screening patient populations found in the clinical laboratories.

2. Special Conditions for Use Statement:

   For Prescription Use Only

H. Substantial Equivalence Information:

1. Predicate Device Name and 510(k) number:

   MICRO21 with Urine Sediment Analysis; K982301

2. Comparison with Predicate Device:

Similarities		
Item	Device Sysmex UD-10	Predicate Micro21 with Urine Sediment Analysis
Intended Use	The Sysmex UD-10 is a Fully Automated Urine Particle Digital Imaging Device for locating, digitally storing and displaying microscopic images captured from urine specimens. The Sysmex® UD-10 locates and presents particles and cellular elements based on size ranges. The images are displayed for review and classification by a qualified clinical laboratory technologist on the Urinalysis Data Manager (UDM). This device is intended for in vitro diagnostic use in conjunction with a urine particle counter for screening patient populations found in clinical laboratories.	Intelligent Medical Imaging, Inc.'s MICR021® with Urine Sediment Analysis is a laboratory instrument for locating, digitally storing and displaying microscopic fields of view from urine sediments in a urine slide for examination by a qualified individual for use in reporting a urine microscopic result.
Regulation	21 CFR 864.5260	Same

Similarities		
Item	Device Sysmex UD-10	Predicate Micro21 with Urine Sediment Analysis
Product Code	JOY	Same
Device Classification Name	Automated Cell Locating Device	Same
Specimen Type	Urine	Same

Differences		
Item	Device	Predicate
Sample Preparation	None; the device analyzes uncentrifuged urine.	Slides prepared from resuspension of fresh urine sediment.
Staining	No staining performed.	Sternheimer-Malbin stain is added to the sediment prior to placement upon the slide.

I. Special Control/Guidance Document Referenced (if applicable):

CLSI EP12-A2, User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition. 2008.

CLSI Document EP05-A3. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition. 2014.

CLSI Document EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures; A Statistical Approach; Approved Guideline - Third Edition

CLSI Document EP17-A2. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline--Second Edition. 2012

IEC 61326-2-6:2005 Electrical equipment for measurement, control, and laboratory use - EMC requirements - Part 2-6: Particular requirements -0 In vitro diagnostic (IVD) medical equipment

IEC60825-1: Safety of Laser Products - Part 1: Equipment Classification, And Requirements [Including: Technical Corrigendum (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]

IEC 61010-1: Safety Requirements For Electrical Equipment for Measurement, Control, And Laboratory Use-Part 1: General Requirements [Including: Corrigendum 1 (2011)]

IEC 61010-2-081:2001+A 1 Safety requirements for electrical equipment for measurement, control and laboratory use-Part 2-081: Particular requirements for automatic and semi-

automatic laboratory equipment for analysis and other purposes

IEC 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control and laboratory use-Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy:

Method Comparison

A method comparison study was conducted to compare the Sysmex UD-10 to manual microscopy with normal and abnormal urine samples. The study was conducted at four U.S. sites using 746 unique residual urine samples, collected without preservatives from patients undergoing routine urinalysis. The patient demographics included patients from 6 days old to 96 years of age and comprised of 366 males and 380 females. The identification of the presence of elements (red blood cells; RBCs, white blood cells; WBCs, crystals, epithelial cells, bacteria (microorganisms), casts and miscellaneous elements) using the UD-10 and manual microscopy was evaluated per element (cell/particle group) by site and for all sites combined.

The results of the agreement analysis between the UD-10 and manual microscopy for all cell/particle groups and sites combined are provided in the following table. The comparison is provided as overall agreement, positive percent agreement (PPA) and negative percent agreement (NPA) along with the 95% confidence interval for overall cell/particle groups and sites.

		Manual Microscopy		
		Present (Positive)	Absent (Negative)	Total
Sysmex UD-10	Present (Positive)	652	43	695
	Absent (Negative)	17	34	51
	Total	669	77	746

PPA = 652/(652+17) x 100 = 97.5% (96.0%, 98.4%)
NPA = 34/(34+43) x 100 = 44.2% (33.6%, 55.3%)
Overall agreement = (652+34)/746 = 92.0% (89.8%, 93.7%)

b. Precision/Reproducibility:

Repeatability

A repeatability study was conducted at four U.S. sites using both normal and abnormal urine samples, collected without preservatives. Five replicates were performed for each sample. Two technologists independently reviewed and identified the particle images displayed in each class (one to eight) for each sample run. Each technologist's results were treated and recorded as an independent observation. The following operator classifications were evaluated: RBCs, WBCs, crystals, epithelial cells, bacteria (microorganisms), casts and miscellaneous elements. Overall agreement with the 95% CI was calculated and provided: 100% (97.8%, 100%). The results of the repeatability study were determined to be acceptable.

Reproducibility

Reproducibility studies were performed to determine if technologists can use the UD-10 device to reproducibly identify the presence of elements in an abnormal quality control (QC) sample (L2), and the absence of elements in normal QC (L1) sample over time. The objective will be numerically achieved if the overall % agreement exceeds 80.9% between the UD-10 and QC results (L1/L2) over all sites and collection days for the per protocol analysis population. The study was conducted at four (4) US clinical sites using commercially available MAS® UA control material (Level 1 and Level 2). Three aliquots of each level of control was poured into sample tubes, barcoded with a unique identifier and processed in a random order on the UD-10. The samples were processed twice per day for a minimum of five non-consecutive days. One technologist reviewed and identified particle images (RBCs and WBCs) displayed in each class (one to eight) and recorded the results of each sample.

Cell/Particle Group	Site	PPA (95% CI)	NPA (95% CI)	Overall Agreement (95% CI)
All	01	100.0% (88.6%, 100.0%)	96.7% (83.3%, 99.4%)	98.3% (91.1%, 99.7%)
	04	100.0% (88.6%, 100.0%)	90.0% (74.4%, 96.5%)	95.0% (86.3%, 98.3%)
	05	100.0% (88.6%, 100.0%)	100.0% (88.6%, 100.0%)	100.0% (94.0%, 100.0%)
	06	100.0% (88.6%, 100.0%)	96.7% (83.3%, 99.4%)	98.3% (91.1%, 99.7%)
RBCs	01	100.0% (88.6%, 100.0%)	100.0% (88.6%, 100.0%)	100.0% (94.0%, 100.0%)
	04	100.0% (88.6%, 100.0%)	96.7% (83.3%, 99.4%)	98.3% (91.1%, 99.7%)
	05	100.0% (88.6%, 100.0%)	100.0% (88.6%, 100.0%)	100.0% (94.0%, 100.0%)
	06	100.0% (88.6%, 100.0%)	100.0% (88.6%, 100.0%)	100.0% (94.0%, 100.0%)
WBCs	01	100.0% (88.6%, 100.0%)	96.7% (83.3%, 99.4%)	98.3% (91.1%, 99.7%)
	04	100.0% (88.6%, 100.0%)	93.3% (78.7%, 98.2%)	96.7% (88.6%, 99.1%)

	05	100.0% (88.6%, 100.0%)	100.0% (88.6%, 100.0%)	100.0% (94.0%, 100.0%)
	06	100.0% (88.6%, 100.0%)	96.7% (83.3%, 99.4%)	98.3% (91.1%, 99.7%)

c. Linearity:

Not applicable

d. Carryover:

Carryover studies were conducted is to determine if visual diagnostic carryover was present in low concentration samples (normal samples) when preceded by high concentration samples (abnormal samples) in consecutive order.

The study was conducted at four U.S. sites to determine carryover for bacteria (BACT) and three sites to determine carryover of WBCs and RBCs using residual urine samples, collected without preservatives, with high concentrations of WBCs, RBCs and bacteria (High Sample) and low concentrations of WBCs, RBCs and bacteria (Low Sample). Sample selection was determined based on the Sysmex UF-1000i results. Urine samples with WBC, RBC and bacteria counts near the upper measurement range were used as the High Sample and urine samples with WBCs, RBCs and bacteria counts near the lower measurement range were used as the Low Sample for this study.

Each sample was mixed, split into three separate sample aliquot tubes (three high sample aliquots and three low sample aliquots), and then barcoded with a unique identifier. The three high concentration samples were assayed on the UD-10 in consecutive order, immediately followed by the three low concentration samples. A technologist reviewed images displayed in each class (one to eight) from each low sample and recorded the results of their findings as present/absent to indicate the presence or absence of WBCs, RBCs and Bacteria of each low sample.

e. Interfering Substances:

Not applicable

2. Other Supportive Instrument Performance Data Not Covered Above:

Not applicable

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.