October 30, 2018

Sysmex America, Inc.
Jessica Rivera-Montejo
Regulatory Affairs Project Manager
577 Aptakisic Road
Lincolnshire, Illinois 60069

Re: K182062
Trade/Device Name: Sysmex UD-10 Fully Automated Urine Particle Digital Imaging Device
Regulation Number: 21 CFR 864.5260
Regulation Name: Automated cell-locating device
Regulatory Class: Class II
Product Code: JOY
Dated: July 31, 2018
Received: August 1, 2018

Dear Jessica Rivera-Montejo:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology
and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Sysmex® UD-10 Fully Automated Urine Particle Digital Imaging Device

Indications for Use *(Describe)*
The Sysmex® UD-10 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.

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 summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K182062.

807.92 (a)(1): Name: **Jessica Rivera-Montejo**
Address: 577 Aptakisic Rd.
Lincolnshire,IL 60069

Phone: **(224)543-9650**
Email: riveramontej@sysmex.com
Contact: **Jessica Rivera-Montejo**

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name:
Sysmex UD-10 Fully Automated Urine Particle Digital Imaging Device

Common Name: Automated cell-locating device (urine sediments)

Classification: 21 CFR 864.5260

807.92 (a)(3): Identification of the legally marketed predicate devices
MICRO21 with Urine Sediment Analysis (Triangle Biomedical Sciences, Palm Beach Gardens, FL), cleared under K982301.

807.92 (a)(4): Device Description

The Sysmex® UD-10 is a medical device that captures images of cells and particles found in urine with a camera and displays the images on a display screen. The displayed data consists of images of individual particles that are extracted from the original captured whole field images. The device sorts urine particle images based on their size into eight groups (Class 1-8). These images are transferred to the UDM (Urinalysis Data Manager), where the operator enters the classification of the particle images based on their visual examination. The classification of the particles by the operator is a designation of what type of particles are observed (e.g., WBCs, RBCs, casts, bacteria).

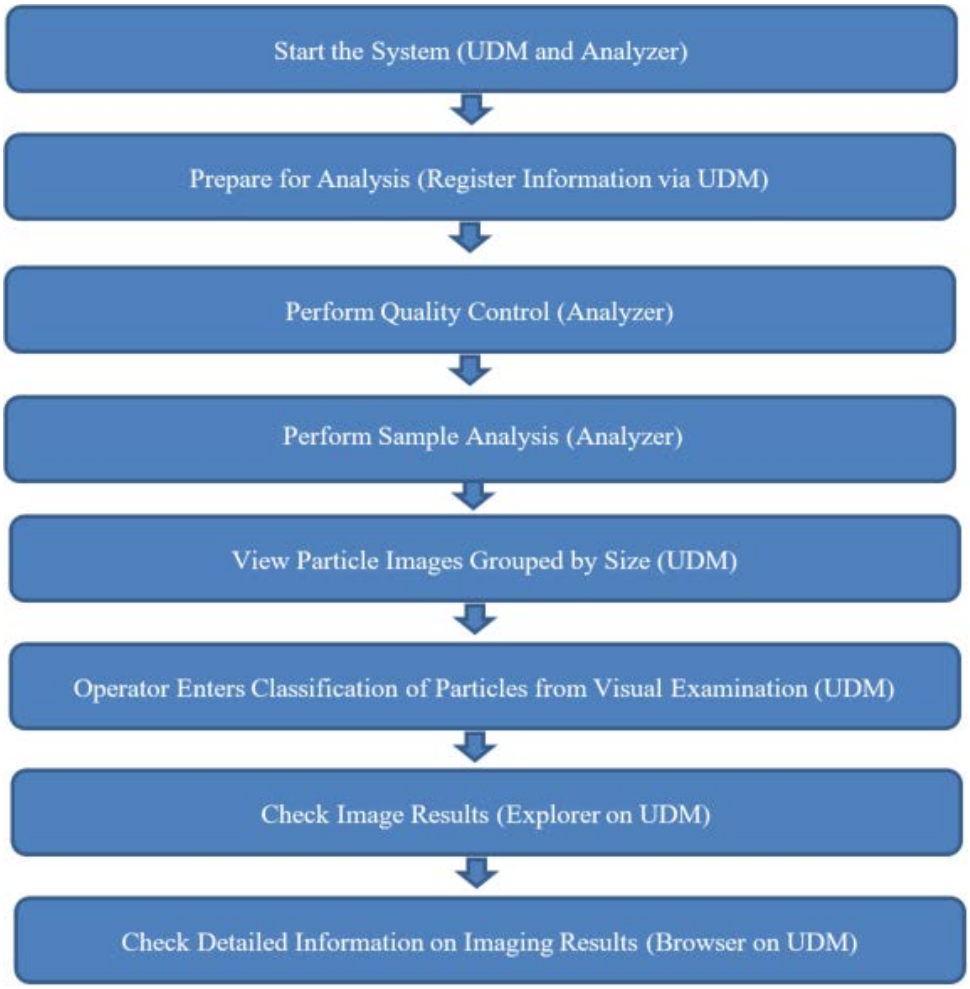
The size ranges of cells and particles that fall under each size group (Class 1-8) are provided below, along with the number of display images for each group.

Size Range and Number of Display Images

Size Group	Size Range (µm)	Number of display images
Class 1	2-6	100
Class 2	6-10	100
Class 3	10-16	100
Class 4	16-36	50
Class 5	36-71	50
Class 6	71-101	20
Class 7	101-151	20
Class 8	151 or more	20

An overview of the basic operation of the Sysmex® UD-10 device is provided in below.

Overview of Sysmex® UD-10 Device Basic Operation



807.92 (a)(5): Intended Use

The Sysmex® UD-10 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.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

The Sysmex UD-10 is substantially equivalent to the Micro21® with Urine Sediment Analysis, K982301.

	Device	**Predicate**
Device	**Sysmex® UD-10**	**MICR021® with Urine Sediment Analysis**
Regulation	864.5260 Class II	Same
Product Code	JOY	Same
Device Classification Name	Automated Cell Locating Device	Same
Intended Use	The Sysmex® UD-10 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.
Specimen Type	Urine	Same
Sample Preparation	None	Slides prepared from resuspension of fresh urine sediment.
Staining	No staining is performed.	Sternheimer-Malbin stain is added to the sediment prior to placement upon the slide.

807.92 (b)(1): Brief Description of Nonclinical Data

Precision- Reproducibility

The objective was 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 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 days (the days were not consecutive). One technologist reviewed and identified particle images (RBCs and WBCs) displayed in each class (one to eight) and recorded the results of each sample.

The results of the precision (reproducibility) study from all sites combined are presented in the table below.

UD-10 Precision (Reproducibility) – Overall Agreement of Cells (WBC, RBC) & Sites

Cell/Particle Group	Site	Time (Days)	PP *	PA *	AP *	AA *	PPA (%) (95% CI) *	NPA (%) (95% CI) *	Overall (%) (95% CI) *
All	All	All	120	5	0	115	100.0% (96.9%, 100.0%)	95.8% (90.6%, 98.2%)	97.9% (95.2%, 99.1%)

* PP: Present in both UD-10 and quality control samples (expected results).
* PA: Present in UD-10 samples and Absent in quality control samples (unexpected results).
* AP: Absent in UD-10 samples and Present in quality control samples (unexpected results).
* AA: Absent in both UD-10 and quality control samples (expected results).

* Positive Agreement (PPA): % and 95% (2-sided) confidence interval on %.
* Negative Agreement (NPA): % and 95% (2-sided) confidence interval on %.
* Overall Agreement (PP + AA): % and 95% (2-sided) confidence interval on %.

Results Conclusion

The reproducibility study, completed for four clinical sites, resulted in a total of 240 evaluations of images displayed on the UD-10 using MAS UA abnormal control material and normal control (containing WBCs and RBCs).

Overall, technologists reported the presence of elements in only five cases when testing the normal control material, which was not element free. The remaining 235 evaluations, inclusive of the 120 cases of negatives (normal), were concordant with the QC material, resulting in 97.9% overall agreement with a 95.2% lower confidence limit. In that this limit exceeds the 80.9% minimum requirement, the reproducibility primary study objective was statistically achieved as planned at 97.5% confidence (1-sided).

Precision (Repeatability)

The study objective was to determine if technologists can use the UD-10 device to repeatedly identify the presence of elements in both abnormal and normal urine samples. The study was conducted at four (4) US clinical sites using normal and abnormal residual urine samples, collected without preservatives. Each site aimed to obtain one abnormal and one normal sample from each cell/particle group as outlined in the below. An individual sample may be representative of one or more cell/particle groups (e.g., RBCs and WBCs). Five replicates of each sample were assayed on the UD-10. Reference results were provided by screening the samples with the Sysmex UF-1000i urine analyzer (K070910).

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.

Urine Sample Cell/Particle Groups – Per CLSI GP16-A3

Group Number	Cell/Particle Group	Urine Sample Contents
1	Microorganisms	Bacteria, Parasites, Yeast, Viral Inclusions
2	Blood Cells	Red Blood Cells
3		White Blood Cells
4	Crystals	Calcium Oxalate, Cholesterol Plates, Cystine, Triple Phosphate, Uric Acid, Amorphous
5	Epithelial Cells	Squamous, Renal Tubular, Transitional
6	Casts	Bacterial, Broad, Cellular, Fatty, Granular, Hyaline, Red Blood Cell, White Blood Cell, Waxy
7	Miscellaneous	Contaminants, Mucus Threads, Sperm

The summarized results from the repeatability testing are shown below.

UD-10 Precision (Repeatability) – Overall Agreement of Cells (All Cells and Particle Groups) & Sites

Cell/Particle Group	Site	Technologist	PP *	PA *	AP *	AA *	PPA (%) (95% CI) *	NPA (%) (95% CI) *	Overall (%) (95% CI) *
All	All	All	170	0	0	0	100.0% (97.8%, 100.0%)	-	100.0% (97.8%, 100.0%)

* PP: Present in both UD-10 and UF-1000i devices (expected results).
* PA: Present in UD-10 device and Absent in UF-1000i device (unexpected results).
* AP: Absent in UD-10 device and Present in UF-1000i device (unexpected results)..
* AA: Absent in both UD-10 and UF-1000i devices (expected results).

* Positive Agreement (PPA): % and 95% (2-sided) confidence interval on %.
* Negative Agreement (NPA): % and 95% (2-sided) confidence interval on %.
* Overall Agreement (PP + AA): % and 95% (2-sided) confidence interval on %.

Results Conclusion

The repeatability study, completed for four clinical sites, resulted in a total of 170 evaluations of abnormal and normal urine samples representing the cell/particle groups: microorganisms, blood cells, epithelial cells, casts, crystals, and miscellaneous.

Overall, technologists correctly reported the presence of elements representing one or more of these cell/particle groups for all sample replicates. This study achieved 100.0% overall agreement. with a 97.8% lower confidence limit. In that this limit exceeds the 85.2% minimum requirement, the repeatability primary study objective was statistically achieved as planned at 97.5% confidence (1-sided).

Carryover

The objective of this study was to determine if visual diagnostic carryover is present in low concentration samples (normal samples) when preceded by high concentration samples (abnormal samples) in consecutive order. The study was conducted at four (4) US sites for BACT and three (3) sites for WBC and RBC 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. The data are presented below.

UD-10 Carryover – Technologist's Visual Review of Images

Parameter	Site	UF-1000i High Sample Cell Count	UF-1000i Low Sample Cell Count	High Sample Replicate 1	High Sample Replicate 2	High Sample Replicate 3	Low Sample Replicate 1	Low Sample Replicate 2	Low Sample Replicate 3
Bact	01	9983.9	7.3	PRESENT	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT
	04	17879.6	37	PRESENT	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT
	05	10145.5	74.7	PRESENT	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT
	06	9517.1	3.5	PRESENT	PRESENT	PRESENT	PRESENT	PRESENT	PRESENT
RBC	01	10314.7	1.4	PRESENT	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT
	04	9967.4	17.8	PRESENT	PRESENT	PRESENT	ABSENT	PRESENT	ABSENT
	05	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	06	9574.6	2.4	PRESENT	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT
WBC	01	5326.1	2.2	PRESENT	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT
	04	4735.7	0.2	PRESENT	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT
	05	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	06	4969.1	0.1	PRESENT	PRESENT	PRESENT	PRESENT	ABSENT	ABSENT

Discussion:
Based on the results of technologists' visual observations of images displayed on the UD-10, Site 06 (bacteria and WBCs), and Site 04 (RBCs) indicated the presence of cell/particles in Low Samples. However, the samples were not "zero" as per the reference testing, and therefore further analysis was undertaken.

Using a logistic regression model, the predicted probabilities of a technologist indicating the presence or absence of elements in low sample replicates, given its concentration value as recorded in the above table (UF-1000i, Low Sample Cell Count), were calculated for each parameter, site and replicate. Probabilities are expected to be close to 1 for high concentration samples, and close to 0 for low concentration samples. These probabilities were then used to compute the carryover effect (%) = 100(L1-L3)/(H3-H3), for Low Sample replicates 1 and 3 and High Sample replicate 3. The acceptance criterion for carryover effect is within ±1.00%. The results of this analysis are provided in the following table.

UD-10 Carryover: Logistic Regression Analysis-Technologist Observation of Bact, RBC and WBC

Parameter	Site	Abnormal Samples			Normal Samples			Carryover Effect (%)	Conclusion
		Replicate 1	Replicate 2	Replicate 3	Replicate 1	Replicate 2	Replicate 3		
RBC	01	> 0.9999	> 0.9999	> 0.9999	2.75E-10	2.75E-10	2.75E-10	9.82E-23	PASS
	04	> 0.9999	> 0.9999	> 0.9999	0.3333	0.3333	0.3333	4.16E-14	PASS
	06	> 0.9999	> 0.9999	> 0.9999	1.34E-09	1.34E-09	1.34E-09	4.55E-22	PASS
WBC	01	> 0.9999	> 0.9999	> 0.9999	1.05E-14	1.89E-34	3.39E-54	1.05E-12	PASS
	04	> 0.9999	> 0.9999	> 0.9999	5.61E-11	1.01E-30	1.81E-50	5.61E-09	PASS
	06	> 0.9999	> 0.9999	> 0.9999	> 0.9999	1.43E-10	2.57E-30	100.00	FAIL
BACT	01	> 0.9999	> 0.9999	> 0.9999	1.10E-11	1.10E-11	1.10E-11	-1.12E-17	PASS
	04	> 0.9999	> 0.9999	> 0.9999	2.53E-20	2.53E-20	2.53E-20	-2.57E-26	PASS
	05	> 0.9999	> 0.9999	> 0.9999	8.68E-12	8.68E-12	8.68E-12	-8.85E-18	PASS
	06	> 0.9999	> 0.9999	> 0.9999	> 0.9999	> 0.9999	> 0.9999	0.00	PASS

Discussion Conclusion
As demonstrated in the above table, the carryover effect for RBC had a site range of $9.82x10^{-23}$% to $4.16x10^{-14}$%. The carryover effect for BACT had a site range of 0.00% to $-2.57x10^{-26}$%. The carryover effect for WBC had a site range of $1.05x10^{-12}$% to 100.00%.

These above results demonstrated that there was no carryover for RBC and BACT for any site but minimal carryover for WBC at Site 06 where the technologist indicated the presence of one (1) WBC seen in the Low Sample #1. The presence of one (1) WBC was determined to be clinically insignificant as it would not shift the patient from one diagnostic group to another.

As standard laboratory practice, the identification of cell/particle images displayed on the UD-10 by a technologist should be used as a part of an overall diagnosis including clinical symptoms and other examination results.

Method Comparison

The objective of the study was to determine if independent technologists, using the UD-10 device and manual microscopy (reference method), can comparably identify the presence of elements in abnormal and normal urine samples. Also, due to the subjective nature of sediment analysis, the UF-1000i was included as a referee method. The identification of the presence of elements using the UD-10 and manual microscopy was evaluated per element (cell/particle group) across sites and by site. This relationship was quantified in terms of positive, negative, and overall % agreement.

The study was conducted at four (4) US clinical sites using residual urine samples, collected without preservatives, from the daily routine laboratory workload. Samples were transferred to two sample tubes without preservatives and de-identified to ensure the identity of the subject was not known. Sample selection for the evaluation included a mix of normal and abnormal samples which were determined based on the Sysmex UF-1000i Urine Particle Counter results, i.e., normal samples (results without flags and within the established reference range) and abnormal samples (results with flags and outside the established reference range). UF-1000i reportable parameters include RBC, WBC, epithelial cells, casts and bacteria, and flagging parameters include pathological cast, crystals, sperm, yeast-like cell and mucus.

One technologist classified cell and formed elements displayed on the UD-10 imaging device, while a second technologist performed classification and identification of cells and formed elements by visual read using the manual light microscopy method All testing was done in a blinded fashion. The time interval between sample analyses on both methods was less than or equal to 1 hour.

<u>Overall Comparison of UD-10 Results to Manual Microscopy Results</u>

The results of the agreement analysis between UD-10 and manual microscopy for all cell/particle groups and sites combined are provided in the following table in accordance with CLSI Document EP12-A2. 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.

Results of UD-10 versus Manual Microscopy- all elements and sites

Cell/Particle Group	Site	PP *	PA *	AP *	AA *	PPA (%) (95% CI) *	NPA (%) (95% CI) *	Overall (%) (95% CI) *
All	All	652	43	17	34	97.5% (96.0%, 98.4%)	44.2% (33.6%, 55.3%)	92.0% (89.8%, 93.7%)

* PP: Present in both UD-10 and manual microscopy (expected results).
* PA: Present in UD-10 device and Absent in manual microscopy (unexpected results).
* AP: Absent in UD-10 device and Present in manual microscopy (unexpected results).
* AA: Absent in both UD-10 and manual microscopy (expected results)

* Positive Agreement (PPA): % and 95% (2-sided) confidence interval on %.
* Negative Agreement (NPA): % and 95% (2-sided) confidence interval on %.
* Overall Agreement (PP + AA): % and 95% (2-sided) confidence interval on %.

Results (all) Conclusion

The method comparison study, completed for four clinical sites, utilized both UD-10 and manual microscopy to evaluate a total of 746 abnormal and normal samples representing the cell/particle groups: RBC, WBC, epithelial cells, casts, crystals, microorganisms and miscellaneous elements.

The overall level of agreement between UD-10 and manual microscopy was 92.0% with 95% (2-sided) confidence interval (89.8%, 93.7%) exceeding the 85.2% proposed requirement. The results demonstrate the UD-10 can be used to identify urine elements in place of manual microscopy.

Per Element Comparison of UD-10 Results to Manual Microscopy Results

The identification of the presence of elements using the UD-10 and manual microscopy was evaluated per element (cell/particle group) across sites and by site. This relationship was quantified in terms of positive, negative, and overall % agreement. The results of the agreement analysis between UD-10 and manual microscopy for microorganisms, RBCs, WBCs, crystals, epithelial cells (ECs), casts and miscellaneous elements for all sites combined and individual sites are provided in the following table.

Per Element Comparison of - UD-10 versus Manual Microscopy

Cell/Particle Group	Site	PP *	PA *	AP *	AA *	PPA (%) (95% CI) *	NPA (%) (95% CI) *	Overall (%) (95% CI) *
Microorganism	All	337	43	144	222	70.1% (65.8%, 74.0%)	83.8% (78.9%, 87.7%)	74.9% (71.7%, 77.9%)
	01	70	16	41	103	63.1% (53.8%, 71.5%)	86.6% (79.3%, 91.6%)	75.2% (69.3%, 80.4%)
	04	43	18	20	97	68.3% (56.0%, 78.4%)	84.3% (76.6%, 89.9%)	78.7% (72.1%, 84.0%)
	05	56	6	83	22	40.3% (32.5%, 48.6%)	78.6% (60.5%, 89.8%)	46.7% (39.3%, 54.3%)
	06	168	3	0	0	100.0% (97.8%, 100.0%)	0.0% (0.0%, 56.1%)	98.2% (95.0%, 99.4%)
RBCs	All	274	111	81	280	77.2% (72.5%, 81.2%)	71.6% (66.9%, 75.9%)	74.3% (71.0%, 77.3%)
	01	76	39	25	90	75.2% (66.0%, 82.6%)	69.8% (61.4%, 77.0%)	72.2% (66.1%, 77.6%)
	04	16	36	18	108	47.1% (31.5%, 63.3%)	75.0% (67.3%, 81.4%)	69.7% (62.6%, 75.9%)
	05	64	28	18	57	78.0% (67.9%, 85.6%)	67.1% (56.5%, 76.1%)	72.5% (65.2%, 78.7%)
	06	118	8	20	25	85.5% (78.7%, 90.4%)	75.8% (59.0%, 87.2%)	83.6% (77.4%, 88.4%)
WBCs	All	422	103	71	150	85.6% (82.2%, 88.4%)	59.3% (53.1%, 65.2%)	76.7% (73.5%, 79.6%)
	01	139	23	24	44	85.3% (79.0%, 89.9%)	65.7% (53.7%, 75.9%)	79.6% (73.9%, 84.3%)
	04	61	27	22	68	73.5% (63.1%, 81.8%)	71.6% (61.8%, 79.7%)	72.5% (65.5%, 78.5%)
	05	90	41	8	28	91.8% (84.7%, 95.8%)	40.6% (29.8%, 52.4%)	70.7% (63.4%, 77.0%)
	06	132	12	17	10	88.6% (82.5%, 92.8%)	45.5% (26.9%, 65.3%)	83.0% (76.7%, 87.9%)
Crystals	All	138	36	67	505	67.3% (60.6%, 73.4%)	93.3% (90.9%, 95.2%)	86.2% (83.5%, 88.5%)
	01	50	16	15	149	76.9% (65.4%, 85.5%)	90.3% (84.8%, 93.9%)	86.5% (81.5%, 90.3%)
	04	31	10	13	124	70.5% (55.8%, 81.8%)	92.5% (86.8%, 95.9%)	87.1% (81.4%, 91.2%)
	05	28	1	20	118	58.3% (44.3%, 71.2%)	99.2% (95.4%, 99.9%)	87.4% (81.5%, 91.6%)
	06	29	9	19	114	60.4% (46.3%, 73.0%)	92.7% (86.7%, 96.1%)	83.6% (77.4%, 88.4%)

Cell/Particle Group	Site	PP *	PA *	AP *	AA *	PPA (%) (95% CI) *	NPA (%) (95% CI) *	Overall (%) (95% CI) *
EC	All	396	107	78	165	83.5% (79.9%, 86.6%)	60.7% (54.7%, 66.3%)	75.2% (72.0%, 78.2%)
	01	129	43	13	45	90.8% (85.0%, 94.6%)	51.1% (40.9%, 61.3%)	75.7% (69.7%, 80.7%)
	04	58	29	12	79	82.9% (72.4%, 89.9%)	73.1% (64.1%, 80.6%)	77.0% (70.3%, 82.5%)
	05	100	15	21	31	82.6% (74.9%, 88.4%)	67.4% (53.0%, 79.1%)	78.4% (71.6%, 84.0%)
	06	109	20	32	10	77.3% (69.7%, 83.4%)	33.3% (19.2%, 51.2%)	69.6% (62.3%, 76.0%)
Casts	All	58	49	49	590	54.2% (44.8%, 63.3%)	92.3% (90.0%, 94.2%)	86.9% (84.2%, 89.1%)
	01	20	22	17	171	54.1% (38.4%, 69.0%)	88.6% (83.3%, 92.4%)	83.0% (77.7%, 87.3%)
	04	4	2	0	172	100.0% (51.0%, 100.0%)	98.9% (95.9%, 99.7%)	98.9% (96.0%, 99.7%)
	05	14	11	18	124	43.8% (28.2%, 60.7%)	91.9% (86.0%, 95.4%)	82.6% (76.2%, 87.6%)
	06	20	14	14	123	58.8% (42.2%, 73.6%)	89.8% (83.6%, 93.8%)	83.6% (77.4%, 88.4%)
Miscellaneous	All	141	37	126	442	52.8% (46.8%, 58.7%)	92.3% (89.5%, 94.3%)	78.2% (75.0%, 81.0%)
	01	7	13	29	181	19.4% (9.8%, 35.0%)	93.3% (88.9%, 96.0%)	81.7% (76.2%, 86.2%)
	04	14	9	12	143	53.8% (35.5%, 71.2%)	94.1% (89.1%, 96.9%)	88.2% (82.6%, 92.2%)
	05	0	0	54	113	0.0% (0.0%, 6.6%)	100.0% (96.7%, 100.0%)	67.7% (60.2%, 74.3%)
	06	120	15	31	5	79.5% (72.3%, 85.1%)	25.0% (11.2%, 46.9%)	73.1% (66.0%, 79.2%)

* PP: Present in both UD-10 and manual microscopy (expected results).
* PA: Present in UD-10 device and Absent in manual microscopy (unexpected results).
* AP: Absent in UD-10 device and Present in manual microscopy (unexpected results).
* AA: Absent in both UD-10 and manual microscopy (expected results).

* Positive Agreement (PPA): % and 95% (2-sided) confidence interval on %.
* Negative Agreement (NPA): % and 95% (2-sided) confidence interval on %.
* Overall Agreement (PP + AA): % and 95% (2-sided) confidence interval on %.

Results (per element) Conclusions

The level of agreement between UD-10 and Manual Microscopy for all sites combined for microorganisms, RBCs, WBCs, crystals, epithelial cells, casts and miscellaneous elements were 74.9%, 74.3%, 76.7%, 86.2%, 75.2%, 86.9% and 78.2% respectively, indicating good agreement between subjective methods.

Comparison of UD-10 versus Manual Microscopy as a Function of UF-1000i

Method Comparison – UD-10 and Manual Microscopy against the UF-1000i

The following compares the results of UD-10 and manual microscopy against UF-1000i results (UF-1000i are the referee results). These results include overall agreement and the associated 95% (2-sided) confidence interval for all samples combined, abnormal samples only, and normal samples only. The data demonstrated good agreement across the three methods.

Results of UD-10 versus Manual Microscopy, with UF-1000i as the Referee

Comparison of UD-10 and Manual Microscopy against the UF-1000i (Across Sites)

Sample Types	UD-10 vs UF-1000i	Microscopy vs UF-1000i
All Samples Combined	93.2% (91.1%, 94.8%)	89.7% (87.3%, 91.7%)
Abnormal Samples Only	99.5% (98.2%, 99.9%)	97.6% (95.6%, 98.7%).
Normal Samples Only	85.3% (81.1%, 88.7%)	79.9% (75.3%, 83.9%)

Comparison of UD-10 and Manual Microscopy against the UF-1000i (By Site)

Samples	Method	Site 01	Site 04	Site 05	Site 06
All Samples Combined	UD-10	96.1% (92.7%, 97.9%)	80.3% (73.9%, 85.5%)	95.8% (91.6%, 98.0%)	100.0% (97.8%, 100.0%)
	Microscopy	91.3% (87.0%, 94.3%)	72.5% (65.5%, 78.5%)	95.2% (90.8%, 97.6%)	100.0% (97.8%, 100.0%)
Abnormal Samples Only	UD-10	100.0% (97.5%, 100.0%)	97.5% (91.2%, 99.3%)	100.0% (96.0%, 100.0%)	100.0% (95.9%, 100.0%)
	Microscopy	98.0% (94.3%, 99.3%)	91.1% (82.8%, 95.6%)	100.0% (96.0%, 100.0%)	100.0% (95.9%, 100.0%)
Normal Samples Only	UD-10	88.8% (80.0%, 94.0%)	66.7% (56.9%, 75.2%)	90.7% (82.0%, 95.4%)	100.0% (95.4%, 100.0%)
	Microscopy	78.8% (68.6%, 86.3%)	57.6% (47.7%, 66.8%)	89.3% (80.3%, 94.5%)	100.0% (95.4%, 100.0%)

807.92 (b)(2): Brief Description of Clinical Data

Not applicable

807.92 (b)(3): Conclusions from Nonclinical and Clinical Data

The conclusions drawn from the data demonstrate that the device is safe and effective for its intended use.