

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

A. 510(k) Number:

K070910

B. Purpose for Submission:

This traditional 510(k) is for a modification of a previously cleared device.

C. Manufacturer and Instrument Name:

Sysmex America, Inc., Sysmex® UF-1000i, Automated Urine Particle Analyzer

D. Type of Test or Tests Performed:

The device is a dedicated system for the analysis of microscopic formed elements in urine specimens. The parameters are: RBC, WBC, Epithelial Cells, Casts, Bacteria, and flags the presence of Casts, Crystals, Sperm, Small Round Cells, Yeast like cells, and Mucus.

E. System Descriptions:

1. Device Description:

The Sysmex UF-1000i, an automated urine particle analyzer, is a dedicated system for the analysis of microscopic formed elements in urine specimens. The instrument consists of three principal units; (1) Main unit which aspirates, dilutes, mixes analyzes urine samples; (2) Auto Sampler Unit supplies samples to the Main Unit automatically; (3) IPU (Information Processing Unit) which processes data from the Main Unit and provides the operator interface with the system. The UF-1000i is equipped with a Sampler that provides continuous automated sampling for up to 50 tubes.

2. Principles of Operation:

The instrument utilizes Sysmex flow cytometry using a red semiconductor laser for analyzing organized elements of urine particle characterization and identification is based on detection of forward scatter, fluorescence, and adaptive cluster analysis. Using its own reagents, the UF1000i automatically classifies organized elements of urine and carries out all processes automatically from aspiration of the sample to outputting the results.

3. Modes of Operation:

Manual Mode Measurement and Sampler Mode Measurement

4. Specimen Identification:

Bar Code

5. Specimen Sampling and Handling:

Automated sampling and mixing with a throughput of 100 samples/hour.

6. Calibration:

UFII Calibrator. Calibration is done at the factory. There is no user calibration.

7. Quality Control:

UFII Control (2 levels), QC programs includes L-J management and X-bar management.

8. Software:

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

Yes X or No _____ Software documentation at a Moderate Level of Concern conforms to the FDA software guidance.

F. Regulatory Information:

1. Regulation Section:

21 CFR 864.5200 Automated cell counter

2. Classification:

Class II

3. Product code:

LKM

4. Panel:

Hematology (81)

G. Intended Use:

1. Indication(s) for Use:

Sysmex UF-1000i is an automated urine particle analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The UF-1000i analyzes the following parameters in urine samples: RBC, WBC, Epithelial Cells, Cast, and Bacteria and flags the presence of the following: Pathologic Cast, Crystal, Sperm, Small Round Cell, Yeast-like cell and Mucus.

2. Special Conditions for Use Statement(s):

N/A

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

Sysmex UF-100 (K961054)

2. Comparison with Predicate Device:

| Similarities | | |
|---------------|---------------------|-----------|
| Item | Device | Predicate |
| Specimen Type | Random urine sample | Same |
| Throughput | 100 samples/ hour | Same |

| Differences | | |
|-------------|--|--|
| Item | Device | Predicate |
| Parameters | RBC, WBC, Epithelial Cells, Cast, and Bacteria and flags the presence of the following: Pathologic Cast, Crystal, Sperm, Small Round Cell, Yeast-like cell. | RBC, WBC, Epithelial Cells, Cast, and Bacteria and flags the presence of the following: Pathologic Cast, Crystal, Sperm, Small Round Cell, Yeast-like cell. |
| Methodology | The device utilizes Sysmex flow cytometry using a red semiconductor laser for analyzing organized elements of urine. Particle characterization and identification is | The UF100 utilizes Sysmex flow cytometry using an argon laser for analyzing organized elements of urine. In combination with flow cytometry the UF-100 uses an impedance |

| Differences | | |
|----------------------------------|--|---|
| Item | Device | Predicate |
| Reagents | based on detection of forward scatter, fluorescence, and adaptive cluster analysis. The UF-1000i uses the addition of a new bacteria channel and side scatter light signal. UFII SHEATH UFII SEARCH-SED UFII PACK-SED UFII SEARCH-BAC UFII PACK-BAC | measurement using a double stain with two fluorescent dyes. Particle characterization and identification is based on detection of forward scatter, fluorescence and impedance signals, and on adaptive cluster analysis. URINOSEATH URINOSSEARCH URINOPACK |
| Quality Control/ Calibrator | UFII CONTROLS-2 levels UFII CALIBRATOR | UF-CHECK-3 levels UF-CAL |
| Software/Hardware Differences | Two channels for bacteria and sediment | One channel for sediment only |

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

Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA, December 4, 2001

J. Performance Characteristics:

1. Analytical Performance:

a. Accuracy: The UF1000i was compared with the UF100. Specimens included 310 urine samples with various abnormal conditions and normal samples at three outside clinical sites. Linear regression analysis was used for the correlation for RBC, WBC, EC, and CAST parameters. Percent agreement was performed for the Bacteria parameter. A new reference interval was established for the bacteria parameter in the UF-1000i since there is a separate channel and additional stain in the UF-1000i for bacteria detection. Therefore, a comparison between the UF-1000i and UF-100 using each instrument's bacteria reference interval as the cutoff

exhibited the percent agreement between the two instruments.

Table 1: UF-1000i vs. UF100 Enumerated Parameter Comparison

| Parameter | Correlation (r) | Regression (r ²) | Regression Equation | Range |
|-----------|-----------------|------------------------------|---------------------|------------|
| RBC | 0.9921 | 0.9842 | y=0.9544x-3.009 | 0.0-4628.1 |
| WBC | 0.9669 | 0.9348 | y=0.8622x-1.6818 | 0.0-2557.5 |
| EC | 0.9777 | 0.9558 | y=0.8646x-0.1134 | 0.0-176.5 |
| CAST | 0.9558 | 0.9136 | y=0.6125x-0.0629 | 0.00-28.04 |

Table 2: UF-100i vs. UF100 Bacteria Parameter Comparison

| | |
|---------------------------|--------|
| % Agreement | 83.22% |
| Predictive Value Positive | 91.66% |
| Predictive Value Negative | 84.30% |

Table 3: Overall Flagging Parameter Comparison: A flagging comparison of the UF-1000i to the UF-100 was performed on 310 samples. The flagging of the UF-1000i was also compared to the manual microscopic samples on 71 samples.

| | UF-1000i vs. UF-100 | UF-1000i vs. Manual |
|----------------------------------|---------------------|---------------------|
| % Agreement= $\frac{TP + TP}{N}$ | 91.29% | 81.69% |
| N | | |

Conclusion: the UF-000i results compared favorably with UF-100 results.

- b. *Precision/Reproducibility:* Within run precision data was collected for the quality control material (Lot # A6006) for the five enumerated parameters (RBC, WBC, Epithelial Cells, Cast, and Bacteria). Ten consecutive replicates of QC levels L and H were tested on the UF-1000i. The mean, standard deviation and coefficient of variation were determined and compared to performance claims on the assay sheet.

Table 4: Within Run Precision using QC Material (Lot # A6006)

| UFII-L Lot # A6006 | | | | | |
|--------------------|------|------|------|------|----------|
| | RBC | WBC | EC | Cast | Bacteria |
| Mean | 37.9 | 40.5 | 11.0 | 5.4 | 202.7 |
| SD | 4.7 | 5.0 | 1.4 | 0.9 | 17.3 |
| CV% | 12.3 | 12.4 | 12.8 | 17.2 | 8.5 |
| Acceptable | Yes | Yes | Yes | Yes | Yes |

| UFII-H Lot # A6006 | | | | | |
|--------------------|-------|-------|------|------|----------|
| | RBC | WBC | EC | Cast | Bacteria |
| Mean | 200.7 | 814.2 | 75.6 | 19.2 | 796.1 |
| SD | 4.7 | 9.2 | 4.0 | 1.4 | 34.6 |
| CV% | 2.3 | 1.1 | 5.3 | 7.1 | 4.4 |
| Acceptable | Yes | Yes | Yes | Yes | Yes |

Within Run Urine Specimens: Within Run precision was determined on select urine specimens each having a minimum volume of 50 mL which exceeded the established Normal population Reference Range for the five enumerated parameters (RBC, WBC, EC, CAST, Bacteria). The specimens were analyzed 10 times consecutively on the UF-1000i in the manual mode.

Conclusion: The within run precision on the five enumerated parameters were acceptable.

- d. *Carryover*: Carryover data was collected by analyzing a high sample three consecutive times (H1, H2, H3) then analyzing a low sample three times (L1, L2, L3). The formula $(L1-L3)/(H3-L3) \times 100\%$ was used where L1 is the first low sample analyzed; L3 is the last low sample analyzed; and H3 is the last high sample analyzed.

Table 5: UF-1000i Carryover

| Parameter | Carryover | Carryover | Carryover | Carryover | Manufacturer Specification |
|-----------|-----------|-----------------------|-----------|---------------|---|
| RBC | 0.05% | 0.08% | 0.09% | 0.05% | $\leq 0.1\%$ or $\leq 5.0/\mu\text{L}$ |
| Bacteria | 0.00% | 0.0012/ μL | 0.00% | 0.0035/ μ | $\leq 0.05\%$ or $\leq 5.0/\mu\text{L}$ |

Conclusion: Carryover on the testing parameters met manufacturer specifications.

- e. *Interfering Substances*: The following conditions can volume settings to be difficult: High density samples within pyuria; macroscopic hematuria samples; samples that include fluorescent matter due to the inclusion of crystals or chemicals; samples that include preservatives.

2. Other Supportive Instrument Performance Data Not Covered Above:

Linearity: Linearity was performed on RBC, WBC, EC, Cast, and Bacteria by diluting samples with instrument diluent.

Table 6: Linearity Results

| Parameter | Range Tested | L | R ² | r | Slope | Intercept |
|-----------------|---------------|-----|----------------|------|-------|-----------|
| WBC | 0.0-3603.0 | /μL | 0.99 | 1.00 | 1.02 | 48.24 |
| | 0.6-1623.3 | /μL | 1.00 | 1.00 | 0.99 | -3.61 |
| | 1.9-5259.7 | /μL | 1.00 | 1.00 | 0.99 | 138.15 |
| RBC | 0.0-5030.9 | /μL | 1.00 | 1.00 | 1.00 | 15.34 |
| | 1.8-2568.3 | /μL | 1.00 | 1.00 | 1.00 | 4.58 |
| | 2.8-5249.1 | /μL | 1.00 | 1.00 | 1.00 | -115.30 |
| EC | 0.3-171.3 | /μL | 0.90 | 1.00 | 1.07 | 12.67 |
| | 3.2-250.9 | /μL | 1.00 | 0.95 | 1.00 | 5.06 |
| CAST | 0.06-5.57 | /μL | 1.00 | 1.00 | 1.00 | -061 |
| | 0.0-15.20 | /μL | 0.94 | 0.97 | 0.95 | -0.73 |
| Bacteria | 0.0-320.2 | /μL | 0.99 | 1.00 | 0.97 | -1.19 |
| | 144.1-6263.75 | /μL | 1.00 | 1.00 | 0.99 | 125.62 |

Conclusion: RBC, WBC, EC, Cast, and Bacteria parameters were linear.

Verification of Reference Intervals: Since the UF-1000i is similar to the UF-100, 169 urine specimens fulfilling sample requirement conditions or the laboratory were tested and compared to existing reference values.

Table 7: Reference Interval Data Collected for UF-1000i

| Parameter | Female Reference Range | Male Reference Range | Combined Reference Range |
|-----------------|------------------------|----------------------|--------------------------|
| RBC | 0-23.6 | 0-7.3 | 0-23.6 |
| WBC | 0-19.0 | 0-10.1 | 0-19.0 |
| EC | 0-33.9 | 0-3.0 | 0-31.2 |
| CAST | 0-0.86 | 0-0.61 | 0-11.1 |
| BACTERIA | 0-993.9 | 0-14.6 | 0-1175.8 |

Table 8: Reference Intervals for UF-1000i

| RBC | WBC | EC | CASTS | BACTERIA |
|------------|------------|-----------|--------------|-----------------|
| < 23/μL | < 25/μL | < 31/μL* | < 1/μL | < 1200/μl |

*Epithelial cell data is considered for information only given these cells are urinary contaminate are dependent on how the urine was collected.

Conclusion: The existing UF100 reference intervals for RBC, WBC, EC, and Casts can be used for the UF-1000i. The reference interval for Bacteria on the UF-1000i has been reestablished due to better bacteria detection with the addition of the bacteria channel and specific bacteria stain in the UF-1000i instrument.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

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

