April 23, 2018

Sysmex America, Inc.
Sharita Brooks
Senior Manager, Regulatory Affairs
577 Aptakisic Road
Lincolnshire, Illinois 60069

Re: K171883
Trade/Device Name: Sysmex UF-5000 Fully Automated Urine Particle Analyzer
Regulation Number: 21 CFR 864.5200
Regulation Name: Automated cell counter
Regulatory Class: Class II
Product Code: LKM
Dated: June 23, 2017
Received: June 23, 2017

Dear Sharita Brooks:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171883

Device Name
Sysmex® UF-5000 Fully Automated Urine Particle Analyzer

Indications for Use *(Describe)*
The Sysmex® UF-5000 Fully Automated Urine Particle Analyzer is an automated urine particle analyzer for in vitro diagnostic use in screening patient populations found in clinical laboratories. The Sysmex® UF-5000 Fully Automated Urine Particle Analyzer analyzes the following parameters in urine samples: RBC, WBC, Epithelial cells, Cast, Bacteria and flags the presence of the following: Pathologic Cast, Crystals, Sperm, Yeast like cell and Mucus.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary for the Sysmex® UF-5000 Fully Automated Urine Particle Analyzer is provided below.

1. SUBMITTER

Sysmex America Inc. (SAI)
577 Aptakisic Road
Lincolnshire, IL 60069

Contact Person: Sharita Brooks
Phone: 224-543-9618
Email: brookss@sysmex.com
Date Prepared: June 21, 2017

2. DEVICE

Name of Device: Sysmex® UF-5000 Fully Automated Urine Particle Analyzer
Common Name: Automated Cell Counter
Classification Regulation: 21 CFR 864.5200
Regulatory Class: II
Product Code: LKM
Panel: Hematology

3. PREDICATE DEVICE

Predicate Device: Sysmex® UF-1000i, Automated Urine Particle Analyzer (K070910)

No reference devices were used in this submission.

4. DEVICE DESCRIPTION

The Sysmex® UF-5000 Fully Automated Urine Particle Analyzer is an automated urine particle analyzer that is used in the clinical laboratory to analyze formed elements in urine samples quantitatively and flag for the presence of particles/cells in the sample. It provides screening of abnormal samples, as well as automation and better efficiency in the laboratory. The analyzer reports analysis results on five enumerated parameters in urine: RBC (Red Blood Cells), WBC (White Blood Cells), EC (Epithelial Cells), CAST and BACT (Bacteria). It also reports flagging information on the following parameters in urine: Pathologic Cast; Crystal; Sperm; Yeast like cell; and Mucus. This flagging information alerts the operator for the need of further testing and/or review.

The Sysmex® UF-5000 Fully Automated Urine Particle Analyzer is a dedicated system for the analysis of microscopic formed elements in urine and uses a Microsoft® Windows Operating System. The analyzer consists of the following units: (1) Main Unit which aspirates, dilutes, mixes and analyzes urine samples and processes data from the main unit and provides the

operator interface with the system; (2) Sampler Unit which supplies samples to the main unit automatically; and (3) Pneumatic Unit which supplies pressure and vacuum to the main unit.

The analyzer uses five reagents—UF-CELLSHEATH (sheath reagent), UF-CELLPACK CR and UF-CELLPACK SF (diluents) and UF-Fluorocell CR and UF-Fluorocell SF (both stains). The quality control material is UF-CONTROL.

5. INDICATION FOR USE

The Sysmex® UF-5000 Fully Automated Urine Particle Analyzer is an automated urine particle analyzer for in vitro diagnostic use in screening patient populations found in clinical laboratories. The Sysmex® UF-5000 Fully Automated Urine Particle Analyzer analyzes the following parameters in urine samples: RBC, WBC, Epithelial cells, Cast, Bacteria and flags the presence of the following: Pathologic Cast, Crystals, Sperm, Yeast like cell and Mucus.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Sysmex® UF-5000 Fully Automated Urine Particle Analyzer and its predicate device, the Sysmex® UF-1000i automated urine particle analyzer (K070910), have the same fundamental technology and comparable performance characteristics. The modifications consist of an analyzer with a higher throughput, smaller sample aspiration volume and a smaller minimum particle size detected. Table 1 below compares the subject Sysmex® UF-5000 analyzer with the predicate Sysmex® UF-1000i analyzer.

Table 1: Device Comparison Table

	Predicate Device	**Proposed Device**	**Similarities/ Difference**
510(k) Number	K070910 (SE on May 25, 2007)	---	
Applicant	Sysmex America, Inc.	Sysmex America, Inc.	
Trade Name	Sysmex® UF-1000i, Automated Urine Particle Analyzer	Sysmex® UF-5000, Fully Automated Urine Particle Analyzer	
Classification Regulation	21 CFR 864.5200	21 CFR 864.5200	
Product Code	LKM	LKM	
Indications/ Intended Use	The 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.	The Sysmex® UF-5000 Fully Automated Urine Particle Analyzer is an automated urine particle analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The Sysmex® UF- 5000 Fully Automated Urine Particle Analyzer analyzes the following parameters in urine samples: RBC, WBC, Epithelial cells, Cast and Bacteria and flags the presence of the following:	Similarities: RBC, WBC, Epithelial cells, Cast, Bacteria and flags Pathologic Cast, Crystal, Sperm, Yeast like cells and Mucus. Differences: The Sysmex® UF-5000 does not have a flag for Small Round Cell.

	Predicate Device	**Proposed Device**	**Similarities/ Difference**
		Pathologic Cast, Crystal, Sperm, Yeast like cells and Mucus.	
Parameters	Quantitative parameters: RBC, WBC, Epithelial cells, Cast, Bacteria in urine Flags: Pathologic Cast, Crystal, Sperm, Small Round Cell, Yeast like cell, Mucus	Quantitative parameters: RBC, WBC, Epithelial cells, Cast, Bacteria in urine. Flags: Pathologic Cast, Crystal, Sperm, Yeast like cell and Mucus.	Similarities: Same quantitative parameters. Differences: The Sysmex® UF-5000 does not have a flag for Small Round Cell.
Test Methodology	The instrument utilizes Sysmex® flow cytometry using a red semiconductor laser (wavelength 635nm) for analyzing organized elements of urine. Particle characterization and identification is based on detection of forward scatter, fluorescence and adaptive cluster analysis. There is also a bacteria channel and side scattered light signal.	The instrument utilizes Sysmex® flow cytometry using a blue semiconductor laser (wavelength 488nm) for analyzing organized elements of urine. Particle characterization and identification is based on detection of forward scatter, fluorescence and adaptive cluster analysis. There are two channels- CR channel for WBC, EC, Bacteria and SF channel for RBC, Cast.	Similarities: • Uses Flow Cytometry method to quantitate RBC, WBC, EC, CAST, and BACT • Principles of urine particle analysis • Hydraulic System (Sheath Flow) • Electrical system • Analysis flow • Sensor signal • Particle signal waveform Differences: • Optical system is different: Sysmex® UF-5000 uses a blue semiconductor laser (wavelength: 488nm). • Aspiration, reagent amounts, time & temperature
Reagents	UFII SHEATH (sheath) UFII PACK –SED (diluent) UFII SEARCH –SED (stain) UFII PACK –BAC (diluent) UFII SEARCH –BAC (stain)	UF-CELLSHEATH (sheath) UF-CELLPACK CR (diluent) UF-Fluorocell CR (stain) UF-CELLPACK SF (diluent) UF-Fluorocell SF (stain)	Differences: Reagents
Quality Control	UFII CONTROL—2 levels- 5 parameters	UF-CONTROL—2 levels- 5 parameters	Differences: Controls
Measuring Channels	SED channel: WBC, RBC, EC, CAST BAC channel: Bacteria	CR channel: WBC, EC, Bacteria SF channel: RBC, Cast	Differences: No dedicated channel for bacteria. The non-nucleated parameters are measured in the SF Channel and the nucleated parameters are measured in the CR Channel.
Specimen Type	Random urine specimens	Random urine specimens	Similarities: Urine

	Predicate Device	**Proposed Device**	**Similarities/ Difference**
Throughput	100 samples / hour	105 samples / hour	Similarities: Urine Differences: Higher throughput
Minimum particle size detected	0.633 µm	0.488 µm	Differences: Smaller Particles Detected
Aspiration volume	0.8 mL	0.45 mL	Differences: Smaller sample aspiration
Sample Aspiration/ Fluidic Pathway	Single pathway	Single pathway	Similarities: Single pathway
Dimensions (W x D x H mm)	580 x 710 x 615	760 x 800 x 855 (single sampler)	Differences: Larger analyzer
Weight (kg)	75.5	Approximately: 90	Differences: Heavier analyzer

7. PERFORMANCE DATA

Clinical and analytical validation testing were conducted on the Sysmex® UF-5000 Fully Automated Urine Particle Analyzer to show equivalent performance to the predicate Sysmex® UF-1000i analyzer. Testing included:

- Limits of Blank, Detection, and Quantitation (LoB/LoD/LoQ)
- Linearity
- Precision (Repeatability and Reproducibility)
- Carryover
- Specimen Stability
- Reference Interval
- Method Comparison

Evaluation of the performance characteristics establishes that the performance, functionality, and reliability of the Sysmex® UF-5000 Fully Automated Urine Particle Analyzer are substantially equivalent to the predicate device. The evaluation included accuracy (method comparison), precision, linearity, carryover, stability, LoB, LoD, LoQ, and establishment of reference intervals.

8. CONCLUSIONS

The Sysmex® UF-5000 Fully Automated Urine Particle Analyzer and its predicate device, the Sysmex® UF-1000i automated urine particle analyzer (K070910), have nearly the same Intended Use, fundamental technology, and comparable performance characteristics. The modifications consist of an analyzer with a higher throughput, smaller sample aspiration volume and a smaller minimum particle size detected. The Sysmex® UF-5000 automated urine particle analyzer does

not raise new questions of safety and effectiveness relative to the predicate device. Clinical and analytical validation testing were conducted on the Sysmex® UF-5000 analyzer to show equivalent performance to the Sysmex® UF-1000i analyzer. The evaluation included accuracy (method comparison), precision (repeatability and reproducibility), linearity, carryover, stability, Limits of Blank, Detection, and Quantitation (LoB/LoD/LoQ) and establishment of reference intervals.

Evaluation of the performance characteristics established that the Sysmex® UF-5000 analyzer is substantially equivalent to the Sysmex® UF-1000i analyzer and is suitable for the labeled indication for use.