MAY 25 2007

5. 510(k) SUMMARY of the UF-1000i

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: K070910.

1. Submitted by:	Sysmex America, Inc. One Nelson C. White Parkway Mundelein, IL 60060 Phone: (847) 996-4675; FAX: (847) 996-4655 Contact person: Nina Gamperling Date prepared: March 30, 2007
2. Name of Device:	Trade or proprietary name: Sysmex® UF-1000i Common name: Automated urine particle analyzer. Classification name: Urine Particle Counter (21 CFR 864.5200, Product Code LKM) Related Items: Sheath: UFII SHEATH (Product code: GIF) Stain: UFII SEARCH -SED (Product code: GJH) Diluent: UFII PACK -SED (Product code: GIF) Stain: UFII SEARCH -BAC (Product code: GJH) Diluent: UFII PACK -BAC (Product code: GIF) QC Material: UFII CONTROL (Product code: JIW) Calibrator: UFII CALIBRATOR (Product code: JJW) Option: Graph printer Bar code Reader Rack Sampler Unit (UASU-3/UASU-4) PU-17
3. Predicate Method:	Sysmex® UF-100 (K961054-Cleared October 28, 1996)
4. 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 for three principal units: (1) Main Unit which aspirates, dilutes, mixes and 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. 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 UF-1000i automatically classifies organized elements of urine and carries out all processes automatically from aspiration of the sample to outputting the results. Analysis results and graphics are displayed on the IPU screen. They can be printed on any of the available printers or transmitted to a Host

	computer.
5. 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.
6. Substantial equivalence-Similarities and Differences:	Table 1 shows substantial equivalence of the UF-1000i to the UF-100.
7. Conclusion	The UF-1000i demonstrates substantial equivalence to the predicate device.

Table 1: Substantial Equivalence—Similarities and Difference to UF-100

	Sysmex UF-100	Sysmex UF-1000i	
	Predicate	**Modification of Predicate**	**Similarity/ Difference**
Intended Use	The Sysmex™ UF-100 is intended for *in vitro* diagnostic use in clinical laboratories. The UF-100 analyzes the following parameters: RBC, WBC, Epithelial Cells, Cast, and Bacteria and flags the presence of the following: Pathologic Cast, Crystal, Yeast like cell, Sperm and Small Round Cell.	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 intended use statement is the same. The UF-1000i analyzes the same basic parameters but has the addition of a mucus flag.
Methodology	The instrument 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 measurement. The UF-100 uses flow cytometry with impedance 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.	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. The UF-1000i uses the same methodology as the UF-100 with the addition of a new bacteria channel and side scattered light signal.	Both systems use the same methodology but the UF-1000i has an additional bacteria channel and side scattered light signal.
Reagents	URINOSHEATH URINOSEARCH URINOPACK	UFII SHEATH UFII SEARCH -SED UFII PACK -SED UFII SEARCH -BAC UFII PACK -BAC	The UF-100 reagents have been modified for use on the UF-1000i with the addition of UF II SEARCH -BAC and UF II PACK-BAC for the bacteria channel.
Quality Control/ Calibrator	UF-CHECK—3 levels UF-CAL	UFII CONTROL—2 levels UFII CALIBRATOR	UF-1000i control material has a similar formulation for two

			control levels instead of three. Calibrator material is similar.
Software/ Hardware Differences	One channel for sediment only.	Two channels for bacteria and sediment.	The UF-1000i has a separate channel for the detection of bacteria.
Specimen Type	Random urine sample	Random urine sample	Both systems use the same specimen type.
Throughput	Approx. 100 samples/hour	Same as UF-100	Both systems have the same throughput.
Equivalency Data:	Performance was established in the UF-100 510(k) submission (K961054).	Comparison to the UF-100 demonstrated excellent correlation.	Data consisting of carryover, linearity, accuracy and reproducibility show performance to the manufacturer's specifications. This analysis supports the claim that the UF-1000i is substantially equivalent to the UF-100.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 25 2007

Nina M. Gamperling
Sysmex America, Inc.
One Nelson C. White Parkway
Mundelein, Illinois 60060

Re: k070910
Trade/Device Name: Sysmex ® UF-1000i
Regulation Number: 21 CFR 864.5200
Regulation Name: Automated cell counter
Regulatory Class: Class II
Product Code: LKM
Dated: March 30, 2007
Received: April 2, 2007

Dear Ms. Gamperling:

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.

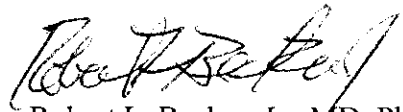
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K070910

Device Name: Sysmex® UF-1000i, Automated Urine Particle Analyzer

Indications 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.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CHRD, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ____

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K070910