JAN 4 2006

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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: K053135.

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: November 4, 2005
2. Name of Device:	Trade or proprietary name: Sysmex® Automated Urine Cell Analyzer, UF-100i Common name: Automated Urine Cell Analyzer. Classification name: Sysmex® UF-100i, Automated Urine Cell Analyzer, is a Urine Particle Counter (21 CFR 864.5200) is a Class II medical device.
3. Predicate Method:	The Sysmex® UF-100i claims substantial equivalence to the UF-100, the predicate method.
4. Device Description:	The Sysmex® UF-100i, automated urine cell analyzer is a dedicated system for the analysis of microscopic formed elements in urine specimens. It accomplishes this by the principles of Laser Flow Cytometry and Impedance. The UF-100i attached to a commercially available reagent strip reader provides all that is required to perform an automated urinalysis profile consisting of chemistries and microscopic results.
5. Intended Use:	The Sysmex® UF-100i is an automated urine cell analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The UF-100i 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.
6. Substantial equivalence-similarities and differences:	The following table compares the UF-100i with the UF-100, the predicate method.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

Comparison Table to Predicate Method

	Sysmex UF-100	**Sysmex UF-100i**
	Predicate	**Modification of Predicate**
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-100i is an automated urine cell analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The UF-100i 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.
Methodology	The UF-100 uses the technique of flow cytometry measuring forward scatter and fluorescence and impedance.	The UF-100i uses the same methodology as the UF-100.
Reagents	URINOSHEATH URINOSEARCH URINOPACK	The UF-100i uses the same reagents as the UF-100.
Software/ Hardware Differences	---	New front upper cover and hinge, no laser transformer, screen and labeling changes.
Specimen Type	Random urine sample	Same as UF-100
Accuracy	Performance was established in the previous 510(k) submission.	Comparison to the UF-100 demonstrated excellent correlation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 4 2006

Ms. Nina M. Gamperling
Manager, Regulatory Affairs
Sysmex American, Inc.
One Nelson C. White Parkway
Mundelein, IL 60060

Re: k053135
Trade/Device Name: Sysmex® UF-100i, Automated Urine Cell Analyzer
Regulation Number: 21 CFR 864.5200
Regulation Name: Automated cell counter
Regulatory Class: Class II
Product Code: LKM
Dated: November 04, 2005
Received: November 08, 2005

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) 276-0484. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K053135

Device Name: Sysmex® UF-100i, Automated Urine Cell Analyzer

Indications For Use:

The Sysmex® UF-100i is an automated urine cell analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The UF-100i 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.

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

Concurrence of CHRD, Office of Device Evaluation (ODE)

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

Robert L Becker

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety