MAY - 2 2008

510(k) SUMMARY of the UF-1000i with Urinalysis WAM

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: K# 080887.

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 28, 2008
2. Name of Device:	Trade or proprietary name: Sysmex® UF-1000i with Urinalysis WAM 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 Urinalysis WAM software
3. Predicate Method:	Sysmex® UF-1000i (K#070910-Cleared May 25, 2007)
4. Device Description and Methodology:	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. Description of Modification:	The modification that was made is the addition of the Urinalysis WAM software on the IPU of the UF-1000i. This software is a modular work area management (WAM) system for data processing and acts as an independent data manager system that interfaces with the UF-1000i and the LIS (Laboratory Information System). This data manager has the capability for patient demographics, test orders and test results. It provides a library of rules for reflex orders for repeats or additional testing.
6. 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.
7. Substantial equivalence-Similarities and Differences:	Design validation studies were completed and sample integrity study was performed. and there is no difference between the UF-1000i and the UF-1000i with Urinalysis WAM software.
8. Conclusion	The UF-1000i with Urinalysis WAM software demonstrates substantial equivalence to the UF-1000i without the Urinalysis WAM software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 2 2008

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

Re: k080887
Trade/Device Name: Sysmex® UF-1000i, Automated Urine Particle Analyzer with Urinalysis WAM
Regulation Number: 21 CFR 864.5200
Regulation Name: Automated Urine Particle Analyzer
Regulatory Class: Class II
Product Code: LKM
Dated: March 28, 2008
Received: April 1, 2008

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 advice for your device on our labeling regulation (21 CFR Part 801), 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). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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/industry/support/index.html.

Sincerely yours,

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

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

Indications for Use

510(k) Number (if known): K080887

Device Name: Sysmex® UF-100i,Automated Urine Particle Analyzer with Urinalysis WAM

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.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K080887

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)