SEP 2 3 2005

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: K051459.

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: September 2, 2005
2. Name of Device:	Trade or proprietary name: Sysmex® XE-2100DC, Automated Hematology Analyzer. Common name: XE-2100DC Classification name: Automated Differential Cell Counter, Sysmex® XE-2100DC (21 CFR 864.5220)
3. Predicate Device:	The Sysmex® XE-2100DC, Automated Hematology Analyzer, is substantially equivalent to the Sysmex XE-2100, Automated Hematology Analyzer.
4. Device Description:	The XE-2100 is an automated hematology analyzer previously cleared by the FDA. XE-2100DC will extend MCV stability to 48 hours. (Note: XE pro software is required to obtain results described.)
5. Intended Use:	The Sysmex XE-2100DC is an automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories and reference laboratories. The XE-2100DC analyzes the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV and NEUT %/#, LYMPH %/#, MONO %/#, EO %/#, and BASO %/#. The XE-2100DC will extend the stability of the MCV parameter in EDTA anticoagulated whole blood samples to 48 hours at 4°C and room temperatures (18-26°C).
6. Substantial equivalence-similarities and differences	The following table compares the XE-2100DC with the predicate method.

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

Comparison Table to Predicate Method

	Sysmex XE-2100	**Sysmex XE-2100DC**
	Predicate	**Modification of Predicate**
Intended Use	The Sysmex™ XE-2100 is a multi-parameter hematology analyzer intended to classify formed elements in anti-coagulated blood. The XE-2100 can provide accurate and precise test results for up to 32 analysis parameters in whole blood.	The Sysmex XE-2100DC is an automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories and reference laboratories. The XE-2100DC analyzes the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV and NEUT %/#, LYMPH %/#, MONO %/#, EO %/#, and BASO %/#. The XE-2100DC will extend the stability of the MCV parameter in EDTA anticoagulated whole blood samples to 48 hours at 4°C and room temperature (18-26°C).
Methodology	The XE-2100 performs hematology analyses using the following methods: RF/DC Detection Method, Sheath Flow DC Detection Method, Flow Cytometry Methods using a Semiconductor Laser and SLS-hemoglobin method.	The XE-2100DC performs hematology analyses using the following methods: Sheath Flow DC Detection Method, Flow Cytometry Methods using a Semiconductor Laser and SLS-hemoglobin method.
Diluting Reagent Differences	CELLSHEATH	CELLSHEATH(C)
Software/ Hardware Differences	---	Hardware: Tubing changes; Heating block modification. Software: Proprietary temperature algorithms
Type of Anticoagulant	EDTA	EDTA
Specimen Type	Peripheral blood	Peripheral blood
Accuracy	Performance was established in the previous 510(k) submission.	Comparison to the XE-2100 demonstrated excellent correlation.

7. Clinical Performance Data: Studies were performed to evaluate the equivalency of XE-2100DC to the predicate method. Results indicated that the XE-2100DC will extend the stability of the MCV parameter in EDTA anticoagulated whole blood samples to 48 hours at 4°C and room temperature (18-26°C).

8. Conclusions: The performance data demonstrated substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Nina M. Gamperling, MBA, MT (ASCP), RAC
Manager, Regulatory Affairs
Sysmex America, Inc.
One Nelson C. White Parkway
Mundelein, Illinois 60060

Re: k051459
Trade/Device Name: Sysmex® XE-2100DC™, Automated Hematology Analyzer
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: August 22, 2005
Received: August 26, 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): K051459

Device Name: Sysmex® XE-2100DC™, Automated Hematology Analyzer

Indications For Use:

The Sysmex XE-2100DC is an automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories and reference laboratories. The XE-2100DC analyzes the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV and NEUT %/#, LYMPH %/#, MONO %/#, EO %/#, and BASO %/#. The XE-2100DC will extend the stability of the MCV parameter in EDTA anticoagulated whole blood samples to 48 hours at 4°C and room temperatures (18-26°C).

(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 ____

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K051459