510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

K051459

B. Purpose for Submission:

Extension of Mean Cell Volume (MCV) parameter stability to 48 hours

C. Manufacturer and Instrument Name:

Sysmex America, Inc., Sysmex XE-2100DC Automated Hematology Analyzer

D. Type of Test or Tests Performed:

Quantitative, Mean Cell Volume (MCV)

E. System Descriptions:

1. Devise Description:

   The Sysmex XE-2100DC is an automated hematology analyzer which can analyze 21 parameters in whole blood. These parameters include: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, and NEUT%/#, LYMP %/#, MONO %/#, EO%/#, and BASO %/#.

   The XE-2100DC system consists of four principle units and three printers, which are: (1) Main unit, which analyzes and controls samples, (2) Sampler Unit, which supplies samples to the Main Unit automatically, (3) Information Processing Unit (IPU), which processes data which gets from the Main Unit, (4) Pneumatic Unit, which supplies pressure and vacuum used by the Main Unit, (5) Color Graphic Printer, which prints a hadcopy of analysis results for screen of histograms, scattergrams, etc, (6) Data Printer, which prints analysis data in the examination ticket format, and (7) Page Printer, which prints lists of analysis information or results. Operator interface with the IPU is accomplished with the use of a 22-key panel keyboard. The analyzer processes approximately 113 to 150 samples per hour, depending on the mode used.

2. Principles of Operation:

   The XE-2100DC performs hematology analyses using the following methods : Sheath Flow DC Detection Method, Flow Cytometry Methods using a Semiconductor Laser and Sodium Lauryl Sulfate (SLS) hemoglobin Method.

WBCs, are analyzed by the opitcal detector block based on the flow cytometry method using a semiconductor laser. RBCs and platelet count are analyzed by the RBC detector using the Hydro Dynamic Focusing (DC Detection) method. Hemoglobin(HBG) is analyzed by the HGB detector based on the SLS-hemoglobin detection method. Analysis data is displayed on the panel keypad LCD screen and IPU.

3. Modes of Operation:

   Manual, Capillary, Sampler (Automatic), Manual Closed

4. Specimen Identification:

   Specimen information is managed by four menu lists and specimen identification input is manual (by operator) or by barcode reader.

5. Specimen Sampling and Handling:

   Whole blood tubes (corresponding to the amount of EDTA anticoagulant) are manually mixed by inversion before sampling.

6. Calibration:

   The manufacturer's instructions are to be followed for materials and frequency of calibration. Following installation calibration, it is requested to verify instrument calibration every six months or on an "as needed " basis, and maintain good QC practices, to ensure the accuracy of the system.

7. Quality Control:

   The manufacturer's instructions are to be followed for materials and frequency of quality control analysis.

8. Software:

   The role of the software on the XE-2100DC analyzer is to operate the instrument in order to analyze whole blood samples and to provide a way to store and review data. One of the software programs allows the user to set user-definable flags according to their laboratory protocol. The XE IPU PIM (Patient Information Manager) software analyzes the data and works in conjunction with the Windows 2000 operating system, which serves as an administrative function.

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes___X___ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 864.5220, Automated Differential Cell Counter

2. Classification:

   Class II

3 Product code:

   GKZ, Counter, Differential Cell

4. Panel:

   Hematology (81)

G. Intended Use:

1. Indication(s) 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-2100 analyzes the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, and NEUT%/#, LYMP %/#, 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^{o}C and room temperature (18^{o}-26^{o}C).

2. Special Conditions for Use Statement(s):

   Not applicable.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   Sysmex XE-2100, K992875

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
	Sysmex XE-2100DC	*Sysmex XE-2100*
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-2100 analyzes the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, and NEUT%/#, LYMP %/#, 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).	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.
Methodology	Analyses using the following methods: Sheath Flow DC Detection Method, Flow Cytometry Methods using a Semiconductor Laser and SLS-hemoglobin method.	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.
Type of Anticoagulant	EDTA	EDTA

Differences		
Item	Device	Predicate
Diluting Reagent	CELLSHEATH (C)	CELLSHEATH

I. Special Control/Guidance Document Referenced (if applicable):

Class II Special Control Guidance Document: Premarket Notification for Automated Differential Cell Counters for Immature or Abnormal Blood Cells Final Guidance for Industry and FDA, December 4, 2001
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 11, 2005

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy:
Accuracy was established by comparing RBC parameters, most specifically the MCV, on the XE-2100DC and the predicate analyzer. 138 samples with

various abnormal conditions were used. The results are as follows:

MCV

Correlation (r)	r^2	Regression
0.98	0.9565	y=0.8849x + 6.0577

b. Precision/Reproducibility:
A minimum of 5 blood samples were assayed 20 consecutive times. The results are as follows:

MCV With-in Run Precision using blood samples

N=20	Mean	SD	CV%
Sample #15	88.17	0.19	0.21
Sample #14	85.40	0.18	0.22
Sample # 13	75.88	0.19	0.26
Sample # 12	78.88	0.19	0.24
Sample #1	90.81	0.17	0.18
Manuf. Specs.			≤1.5%

c. Linearity:
Linearity was evaluated using a series of dilutions of residual patient material. Replicates of three were measured at each level. RBC linearity was generated using greater than 5 levels. The results are as follows:

RBC Linearity results

Correlation (r)	r^2	Regression	Range ($x10^6/\mu L$)
1.00	0.9986	Y=0.0771x-0.0813	0.02-7.68

d. Carryover:
Carryover was evaluated by assaying a sample with high RBC, HGB, HCT and PLT concentration three consecutive times followed immediately by testing a low sample three consecutive times. The test result showed zero carryover.

e. Interfering Substances:
Not applicable.

2. Other Supportive Instrument Performance Data Not Covered Above:

Stability:
28 samples (normal and abnormal) were used to determine stability to 48 hours. Each sample collected was split into 2 aliquots, one held at room temperature (18^o-26^oC) and the other held at low temperature (4^oC). Each sample was analyzed on the XE-2100DC and the designated Reference instrument at baseline (immediately or within 4 hours after blood collection), 24, 48 and 72 hours post collection. MCV results were expressed as percent deviation from the baseline measurement.

The XE-2100DC analyzer result for MCV at 48 hours for both 4°C and room temperature samples exhibited ≤8% deviation.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.