K992875

NOV - 9 1999

510(k) Summary of Safety and Effectiveness Information
SYSMEX™ Automated Hematology Analyzer XE-2100
August 25, 1999

Sysmex Corporation of America
Gilmer Road, 6699 RFD
Long Grove, IL 60047-9596

Contact Person: Nina Gamperling at 847-726-3675 or by facsimile at 847-726-3559

Trade or Proprietary Name: Sysmex™ XE-2100

Common or Usual Name: Automated Hematology Analyzer

Classification Name: Automated Differential Cell Counter 21 CFR 864.5220

Intended Use: The Sysmex™ XE-2100 is a multi-parameter hematology analyzer intended to classify the following formed elements in anti-coagulated blood:

WBC	White Blood Cells count
Neut%	Neutrophil percent
Neut#	Neutrophil absolute count
Lymph%	Lymphocyte percent
Lymph#	Lymphocyte absolute count
Mono%	Monocyte percent
Mono#	Monocyte absolute count
Eo%	Eosinophil percent
Eo#	Eosinophil absolute count
Baso%	Basophil percent
Baso#	Basophil absolute count
NRBC%	Nucleated red blood cell percent
NRBC#	Nucleated red blood cell absolute count
PLT	Platelet count
MPV	Mean Platelet Volume
PDW*	Platelet Distribution Width
P-LCR*	Platelet-Large Cell Ratio
PCT*	Plateletcrit
RBC	Red Blood Cell or erythrocyte count
HGB	Hemoglobin concentration
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Cell Hemoglobin
MCHC	Mean Cell Hemoglobin Concentration
RDW-CV	Red Cell Distribution Width-Coefficient of Variation
RDW-SD	Red Cell Distribution Width-Standard Deviation
RET%	Reticulocyte percent
RET#	Reticulocyte absolute count
IRF	Immature Reticulocyte Fraction
HFR*	High Fluorescence Ratio
MFR*	Medium Fluorescence Ratio
LFR*	Low Fluorescence Ratio

*Not Reportable in USA

Device Description: The XE-2100 is an automated hematology analyzer which consists of four principal units: (1) Main Unit which aspirates, dilutes, mixes, and analyzes whole blood samples; (2) Sampler Unit which 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; (4) Pneumatic Unit which supplies pressure and vacuum from the Main Unit. Additional information on the XE-2100 is presented in Table 1.

Similarities and Differences to Predicate Devices: The Sysmex™ XE-2100 is substantially equivalent in intended use and technological characteristics to previous Sysmex™ instrumentation, the manual differential, and flow cytometry. A summary of the comparative features is presented in Table 1.

Supportive Data: Carryover, precision, linearity, and sample stability data show performance to manufacturer specifications. As demonstrated by correlation studies, the performance claims of the proposed device are similar to the predicate devices, the SE/RAM-1 and SF-3000. During these studies, specimens were evaluated from apparently healthy individuals and from patients with different pathological conditions which are expected to affect the results for particular parameters. In addition, the WBC differential of the XE-2100 was correlated to results from manual differentials performed according to NCCLS H20A and to flow cytometry. The data from these studies supports our claim that the XE-2100 is substantially equivalent to predicate methods.

Conclusion: The Sysmex™ XE-2100 is substantially equivalent to the predicate methods, the SE/RAM-1 and SF-3000.

Table 1: Comparative Features to SE/RAM-1 and SF-3000

Features (Submission #)	XE-2100	SE/RAM-1 (K964375)	SF-3000 (K950508)
FDA Clearance	---	13-Mar-97	3-Nov-95
Intended Use	Automated blood cell analyzer	Automated blood cell counter	Automated blood cell analyzer
Sample Type	Whole blood	Whole blood	Whole blood
Sample Volume	200µL- Cap piercer 130µL -Manual 40µL-Capillary dilution	250µL- Cap piercer 100µL -Manual 40µL-Capillary dilution	270µL- Cap piercer 170µL -Manual 40µL-Capillary dilution
Performance	Same	Proven performance in FDA submission	Proven performance in FDA submission
Parameters	WBC, Neut%/#, Lymph%/ #, Mono%/#, Eos%/#, Baso%/#, NRBC%/#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, RET%/#, IRF, HFR*, MFR*, LFR*, PLT, MPV, PDW*, P-LCR*, PCT* *Not reportable in USA	WBC, Neut%/#, Lymph%/ #, Mono%/#, Eos%/#, Baso%/#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, RET%/#, IRF, PLT, MPV.	WBC, Neut%/#, Lymph%/#, Mono%/#, Eos%/#, Baso%/#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, PDW, MPV, P-LCR.
Reagents	Cellpack, Cellsheath Stromatolyser-FB, Stromatolyser-4DL, Stromatolyser-4DS, Stromatolyser, NR, Stromatolyser-IM, Sulfolyser, Ret-Search II	Cellpack, Cellsheath, Cellpack-3D, StromatolyserWL(II), Stromatolyser-3D, StromatolyserEO(II), Stromalyser-BA, Stromatolyser-IM, Sulfolyser, Ret-Search, Ret-Sheath	Cellpack, Sulfolyzer, StromatolyserFD(I), StromatolyserFD(II), Stromatolyser-FB
Principles	RBC, PLT: Sheath-flow DC detection method, WBC: Flow Cytometry method using semiconductor laser detection method HGB: SLS-Hgb method	RBC, PLT: Sheath-flow DC detection method, WBC: DC Detection Method, RF/DC Detection Method HGB: SLS-Hgb method	RBC, PLT: DC detection method, WBC: Flow using semiconductor laser HGB: SLS-Hgb method
Dimensions (HxWxD) (mm)	711x706x912	720x636x820	600x580x450
Weight (kg)	93	80	60
QC System	L-J: 10 Files with 300 points per file	L-J: 27 Files with 180 points per file	L-J:12 Files with 180 points per file
Bar Code	Yes	Yes	Yes
No. of Test / Hr	Approx 113-150	Approximately 120	Approximately 80

DEPARTMENT OF HEALTH & HUMAN SERVICES

NOV - 9 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Nina Gamperling
Supervisor, Clinical and Regualtory Affairs
Sysmex Corporation of America
Gilmer Road, 6699 RFD
Long Grove, Illinois 60047-9596

Re: K992875
Trade Name: Sysmex™ Automated Hematology Analyzer XE-2100
Regulatory Class: II
Product Code: GKZ
Dated: August 25, 1999
Received: August 26, 1999

Dear Ms. Gamperling:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992875

Device Name: Sysmex ™ Automated Hematology Analyzer XE-2100

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*Not reportable in the USA

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992875

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

Concurrence of CHRD, Office of Device Evaluation (ODE)

Presription Use ✓ **OR Over-The-Counter Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**