SYSMEX CORPORATION
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6699 Wildlife Way
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JUN 2 5 2002

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: K02124 1.

1. Submitted by:	Sysmex Corporation of America 6699 Wildlife Way Long Grove, IL 60047-9596 Phone: (847) 726-3675; FAX: (847) 726-3559 Contact person: Nina Gamperling Date prepared: April 18, 2002
2. Name of Device:	Trade or proprietary name: Sysmex® XT-Series Common name: Automated Hematology Analyzer Classification name: Automated Differential Cell Counter 21 CFR 864.5220
3. Predicate Device:	Sysmex® XE-2100
4. Device Description:	The XT-Series is an automated hematology analyzer which consists of four principle 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 XT is presented in the following table.
5. Intended Use:	The Sysmex® XT-Series is intended for *in vitro* diagnostic use in the clinical laboratory as a multi-parameter hematology analyzer.
6. Substantial equivalence-similarities and differences	The following table compares the XT-Series with the XE-2100.
7. Clinical Performance Data:	Studies were performed to evaluate the equivalency of the XT-Series to the XE-2100. Results indicated equivalent performance.
8. Conclusions:	The performance data demonstrated substantial equivalence.

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

Comparison Table to Predicate Device

Features (Submission #)	XT-Series	XE-2100 (K992875)	SF-3000 (K950508)
FDA Clearance	---	3-Nov-99	3-Nov-95
Intended Use	Automated blood cell analyzer	Automated blood cell analyzer	Automated blood cell analyzer
Sample Type	Whole blood	Whole blood	Whole blood
Sample Volume	150µL- Cap piercer 85µL -Manual 40µL-Capillary dilution	200µL- Cap piercer 130µL -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%/#, 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%/#, 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, PLT, PDW, MPV, P-LCR.
Reagents	Cellpack, Stromatolyser-FB, Stromatolyser-4DL, Stromatolyser-4DS, Sulfolyser, Ret-Search II	Cellpack, Cellsheath Stromatolyser-FB, Stromatolyser-4DL, Stromatolyser-4DS, Stromatolyser, NR, Stromatolyser-IM, Sulfolyser, Ret-Search II	Cellpack, Sulfolyzer, StromatolyserFD(I), StromatolyserFD(II), Stromatolyser-FB
Principles	RBC, PLT: DC detection method, WBC: Flow Cytometry method using semiconductor laser detection method HGB: SLS-Hgb method	RBC, PLT: Sheath-flow DC detection method, WBC: Flow Cytometry method using semiconductor laser detection method HGB: SLS-Hgb method	RBC, PLT: DC detection method, WBC: Flow using semiconductor laser HGB: SLS-Hgb method
Dimensions (HxWxD) (mm)	630x520x720	711x706x912	600x580x450
Weight (kg)	59	93	60
QC System	L-J: 20 Files with 300 points per file	L-J: 10 Files with 300 points per file	L-J: 12 Files with 180 points per file
Bar Code	Yes	Yes	Yes
No. of Test / Hr	Approx 80	Approx 113-150	Approximately 80

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 5 2002

Ms. Nina M. Gamperling, MBA, MT (ASCP), RAC
Manager, Regulatory Affairs
Sysmex Corporation of America
6699 Wildlife Way
Long Grove, Illinois 60047-9596

Re: k021241
Trade/Device Name: Sysmex® XT-Series
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: June 17, 2002
Received: June 18, 2002

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K021241

Device Name: XT-Series, Automated Hematology Analyzer

Indications For Use:

The Sysmex® XT-Series is intended for *in vitro* diagnostic use in the clinical laboratory as a multi-parameter hematology analyzer.

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

Concurrence of CHRD, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021241