AUG 14 1998

K981761

510(k) Summary of Safety and Effectiveness Information
SYSMEX™ Automated Hematology Analyzer KX-21
May 18, 1998

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 847-726-3505

Trade or Proprietary Name: Sysmex™ Automated Hematology Analyzer KX-21

Common or Usual Name: Automated Hematology Analyzer

Classification Name: Automated Cell Counter

Registration Number:

Manufacturer Site
TOA Medical Electronics Co. Ltd, 7010360
Kobe, Japan

Importer and Distributor
Sysmex Corporation of America 1422681
Long Grove, IL 60047-9596

The Sysmex™ KX-21 is substantially equivalent in intended use and technological characteristics to the Sysmex™ K-1000. The KX-21 is an automated blood cell counter intended for *in vitro diagnostic use* in clinical laboratories.

As demonstrated by correlation studies, the performance claims of the proposed device are similar to the predicate device, the K-1000. 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. The following table shows the results of the correlation studies between the proposed and the predicate device.

Correlation Studies to the Sysmex™ K-1000

Parameter	n	r	r^2	Regression Equation
WBC	194	0.990	0.981	y = 0.944x + 0.265
RBC	195	0.996	0.993	y = 1.002x + 0.053
HGB	195	0.997	0.995	y = 0.979x + 0.405
HCT	195	0.996	0.992	y = 0.989x + 1.025
MCV	195	0.997	0.995	y = 0.95x + 4.846
MCH	195	0.967	0.934	y = 0.989x + 0.297
MCHC	195	0.829	0.688	y = 0.813x + 5.935
Platelet	193	0.996	0.993	y = 1.079x - 12.881
Lymph%	150	0.995	0.991	y = 1.017x - 0.072
Mixed%	150	0.874	0.763	y = 1.055x + 1.35
Neut%	150	0.984	0.968	y = 1.011x - 0.292
RDW-SD	198	0.976	0.953	y = 0.942x + 5.96
MPV	179	0.961	0.924	y = 0.947x + 0.611

The following table shows the comparative features of the KX-21 to the Sysmex™ K-1000 and SF-3000.

Comparative Features to K-1000 and SF-3000

Features (Submission #)	KX-21	K-1000 (K882370)	SF-3000 (K950508)
FDA Clearance	---	25-Aug-88	3-Nov-95
Intended Use	Automated blood cell counter for *in vitro diagnostic use* in clinical laboratories	Automated blood cell counter for *in vitro diagnostic use* in clinical laboratories	Automated blood cell differential analyzer for *in vitro diagnostic use* in clinical laboratories
Sample Type	Whole blood	Whole blood	Whole blood
Sample Volume	50µL whole blood 40µL- cap dilution	100µL whole blood 40µL- cap dilution	270µL- Cap piercer 170µL -Manual 40µL-capillary dil
Performance	Similar to K-1000	Proven performance in FDA submission	Proven performance in FDA submission
Parameters	WBC, Lym%/#, MXD%/ # Neu%/ #, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, PDW, MPV, P-LCR	WBC, Lym%/#, MXD%/ # Neu%/ #, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, PDW, MPV	WBC, Lym%/#, Mono%/#, Eos%/#, Baso%/#, Neu%/#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV & SD, PLT, PDW, MPV, P-LCR
Reagents	Cellpack, Stromatolyser-WH	Cellpack, Stromatolyser-3WP, Sulfolyzer	Cellpack, Sulfolyzer, StromatolyserFD(I), Stromatolyser-FD(II), Stromatolyser-FB
Principles	RBC, PLT: DC detection method, WBC: DC detection method HGB: Non-cyanide hgb analysis method	RBC, PLT: DC detection method, WBC: DC detection method HGB: Non-cyanide hgb analysis method	RBC, PLT: DC detection method, WBC: Flow using semiconductor laser HGB: SLS-Hgb method
Dimensions (HxWxD) (mm)	480x420x355	555x480x298	600x580x450
Weight (kg)	28	28	60
QC System	L-J, SD,CV 6 Files, 60 points per file	X bar, 6 Files	L-J, SD,CV 12 Files;180 points per file
Bar Code	Yes	No	Yes
No. of Test / Hour	Approximately 60	Approximately 80	Approximately 80

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 14 1998

Nina Gamperling, MBA, MT(ASCP)
Supervisor, Clinical and Regulatory Affairs
Sysmex Corporation of America
Gilmer Road, 6699 RFD
Long Grove, Illinois 60047-9596

Re: K981761
Sysmex™ Automated Hematology Analyzer KX-21
Regulatory Class: II
Product Code: GKL, GKZ
Dated: July 27, 1998
Received: July 28, 1998

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 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/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):_____

Device Name: Sysmex ™ Automated Hematology Analyzer KX-21

Indications For Use:

The intended use of the Sysmex KX-21 is as an automated cell counter for *in vitro diagnostic use* in clinical laboratories.

(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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number k981761