K032677

FEB 11 2004

Sysmex™

SYSMEX AMERICA, INC.
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510(k) SUMMARY OF SAFETY & EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K032677.

1.	**Submitted By:**	Chris Stukel Sysmex America, Inc. One Nelson C. White Parkway Mundelein, IL 60060 1-847-996-4523 (PHONE) 1-847-996-4499 (FAX) February 4, 2004
2.	**Name of Device:**	Trade Name- Sysmex pocH-100i™ Common Name- Automated Hematology Analyzer Classification Name- Automated Cell Counter
3.	**Predicate Device:**	Sysmex KX-21™
4.	**Device Description:**	The Sysmex pocH-100i is an automated hematology analyzer for use in CLIA non-waived clinical laboratories (not for Point of Care use in a CLIA waived laboratory).
5.	**Intended Use:**	The Sysmex pocH-100i Automated Hematology Analyzer is an automated cell counter intended for *in vitro* diagnostic use in CLIA non-waived clinical laboratories (not for Point of Care use in a CLIA waived laboratory).

6. **Comparison to Predicate:**

	pocH-100i	**KX-21**
Analysis Parameters	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, Lym%, MXD%, Neut%, Lym #,MXD #, Neut #, RDW-SD, RDW-CV, MPV.	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, Lym%, MXD%, Neut%, Lym #,MXD #, Neut #, RDW-SD, RDW-CV, MPV.
WBC Counting Method	DC Detection	DC Detection
RBC/PLT Counting Method	DC Detection w/Hydrodynamic Focusing	DC Detection
HGB Determination Method	Non-Cyanide Hemoglobin Method	Non-Cyanide Hemoglobin Method
Sample Volume Aspirated	15 uL Whole Blood	50 uL Whole Blood
Throughput	Approximately 30 samples/hour	Approximately 60 samples/hour

7. **Clinical Data:** Correlation studies were performed to evaluate the equivalency of the pocH-100i performance compared to the predicate device, the KX-21. The comparison results indicated equivalent performance of the two analyzers, therefore supporting the claim of substantial equivalence.

8. **Conclusions:** The performance data demonstrated substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 11 2004

Mr. Chris Stukel
Regulatory Affairs Specialist
Sysmex America, Inc.
One Nelson C. White Parkway
Mundelein, Illinois 60060

Re: k032677
Trade/Device Name: Sysmex pocH-100i™
Regulation Number: 21 CFR § 864.5200
Regulation Name: Automated Cell Counter (Particle Counter)
Regulatory Class: II
Product Code: GKL, GKZ
Dated: January 26, 2004
Received: January 30, 2004

Dear Mr. Stukel:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Joseph L. Hackett

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
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) K032677

Device Name Sysmex pocH-100i™

Indications for Use

The Sysmex pocH-100i Automated Hematology Analyzer is an automated cell counter intended for *in vitro* diagnostic use in a CLIA non-waived clinical laboratory (not for Point of Care Use in a CLIA waived laboratory). This instrument provides results for the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYM%, MXD%, NEUT%, LYM#, MXD#, NEUT#, RDW-SD, RDW-CV, MPV.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032677

Prescription Use √ OR Over-The-Counter Use _____