AUG 29 2008

# 510(k) SUMMARY of the XS-1000iC

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: K081610 .

**1. Submitted by:**

Sysmex America, Inc.
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Mundelein, IL 60060
Phone: (847) 996-4675; FAX: (847) 996-4655
Contact person: Nina Gamperling
Date prepared: May 30, 2008

**2. Name of Device:**

Trade or proprietary name: Sysmex® XS-1000iC
Common name: Automated Hematology Analyzer.
Classification name:
Sysmex® XS-Series, Automated Hematology, an Automated Differential Cell Counter (21 CFR 864.5220) is a Class II device.
Related Items:

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| CELLSHEATH (C)™ (Diluent) | Product Code: 81GIF |
| STROMATOLYSER-4DL™ (Lyse) | Product Code: 81GGK |
| STROMATOLYSER-4DS™ (Stain) | Product Code: 81KJK |
| SULFOLYSER (Lyse) | Product Code: 81GGK |
| XS Calibrator | Product Code: 81KSA |
| e-Check (Control) | Product Code: 81JPK |

Option: Graphic printer and Bar code Reader

**3. Predicate Method:**

Sysmex® XE-2100DC (K051459-Cleared Sept 23, 2005)

**4. Device Description:**

The Sysmex® XS-1000iC is part of the XS-Series instrument line. It is a multi-parameter hematology analyzer intended to perform tests in anti-coagulated blood. The instrument consists of three principal units: (1) Main Unit which aspirates, dilutes, mixes and analyzes blood samples; (2) Auto Loader that 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.

The XS-Series instruments provide accurate and precise test results for up to 21 analysis parameters in whole blood. These include:

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| WBC | White Blood Cell Count |
| RBC | Red Blood Cell Count |
| HGB | Hemoglobin |
| HCT | Hematocrit |
| MCV | Mean Cell Volume |
| MCH | Mean Cell Hemoglobin |
| MCHC | Mean Cell Hemoglobin Concentration |
| PLT | Platelet Count |
| MPV | Mean Platelet Volume |
| RDW-SD | RBC Distribution Width-SD |
| RDW-CV | RBC Distribution Width-CV |
| NEUT% / # | Neutrophil Percent and Count |
| LYMPH% / # | Lymphocyte Percent and Count |
| MONO% / # | Monocyte Percent and Count |
| EO% / # | Eosinophil Percent and Count |
| BASO% / # | Basophil Percent and Count |

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| | The instrument processes approximately 60 samples per hour, depending on the mode used. The XS display various scattergrams, along with data for the reportable parameters. It displays the following analysis results on the IPU screen: WBC 5DIFF, White blood cells/Basophils, RBC pattern data of cell size distribution curves for platelet and analysis parameters. Analysis results and graphics can be printed on any of the available printers or transmitted to a Host computer. Sample abnormalities are indicated by abnormal marks, flags and error messages which appear on the LCD display screen and on the printout. This is an indication that the sample is not within the acceptable range and requires further review and investigation. There are two discrete testing options---CBC and CBC with Diff.<br><br>The XS performs analyses using the following methods: Sheath Flow DC Detection Method, Flow Cytometry Methods using a Semiconductor Laser and SLS-hemoglobin method. Blood cells pass through the aperature of the detector surrounded by sheath fluid using the sheath flow method. The principle of flow cytometry is also used. A semiconductor laser beam is emitted to the blood cells passing through the flow cell. The forward scattered light is received by the photodiode, and the lateral scattered light and lateral fluorescent light are received by the photo multiplier tube. This light is converted tinto electrical pulses, thus making it possible to obtain blood cell information. Hemoglobin is measured with the SLS-hemoglobin method using Sodium Lauryl Sulfate, which is an analysis method used in our previous instrumentation.<br><br>A modification kit will be installed on a standard XS-1000i instrument where samples >48 hours are analyzed. This modification kit includes software and hardware changes and includes a modified reagent, Cellsheath (C). In this modification, the RBC/PLT dilution process will now be diluted using the Cellsheath (C) reagent after being warmed past 20°C. Software and hardware modifications include changes to the instrument's tubing and modification of the heating block. This only impacts the RBC/PLT dilution step. The WBC and HGB parameters are not impacted. This modification kit was not a change due to recall or corrective action, labeling change, technology or performance change or materials change. |
| **5. Intended Use:** | The Sysmex® XS-1000iC is an automated hematology analyzer for *in vitro* diagnostic use in clinical laboratories and reference laboratories. The XS-1000iC will extend MCV stability to 48 hours. |
| **6. Substantial equivalence-Similarities and Differences:** | Table 1 shows substantial equivalence of the XS-1000iC to the XS-2100DC. |
| **7. Conclusion** | The XS-1000iC demonstrates substantial equivalence to the XE-2100DC. |

**Table 1: Substantial Equivalence—Similarities and Difference to XE-2100DC**

| | Sysmex XE-2100DC | Sysmex XS-1000iC | |
|---|---|---|---|
| | **Predicate** | **Modification of Predicate** | **Similarity/ Difference** |
| **Intended Use** | The Sysmex® XE-2100DC is an automated hematology analyzer for *in vitro* diagnostic use in clinical laboratories and reference laboratories. The XE-2100DC will extend MCV stability to 48 hours. | The Sysmex® XS-1000iC is an automated hematology analyzer for *in vitro* diagnostic use in clinical laboratories and reference laboratories. The XS-1000iC will extend MCV stability to 48 hours. | Both systems have the same intended use. |
| **Methodology** | The XE-2100DC performs analyses using the following methods: Sheath Flow DC Detection Method, and Flow Cytometry Methods using a Semiconductor Laser and SLS-hemoglobin method. | The XS-1000iC performs analyses using the following methods: Sheath Flow DC Detection Method, Flow Cytometry Methods using a Semiconductor Laser and SLS-hemoglobin method. | Both systems use the same methodology. |
| **Reagents** | CELLPACK™ (Diluent)<br>CELLSHEATH (C)™ (Diluent)<br>STROMATOLYSER-FB™ (Lyse)<br>STROMATOLYSER-4DL™ (Lyse)<br>STROMATOLYSER-4DS™ (Stain)<br>STROMATOLYSER-NR™ (Diluent)<br>STROMATOLYSER-NR™ (Stain)<br>STROMATOLYSER-IM™ (Lyse)<br>SULFOLYSER (Lyse) | CELLSHEATH (C)™ (Diluent)<br>STROMATOLYSER-4DL™ (Lyse)<br>STROMATOLYSER-4DS™ (Stain)<br>SULFOLYSER (Lyse) | The XE-2100DC and the XS-1000iC use some of the same reagents. The XS-1000iC does not report out all the parameters that the XE-2100DC does so not all reagents are used on the XS-1000iC. |
| **Quality Control/ Calibrator** | *e*-Check—3 levels<br>XE Calibrator (X Cal) | *e*-Check —3 levels<br>XE Calibrator (X Cal) | The XE-2100DC and the XS-1000iC use the same calibrator and control material |
| **Software/ Hardware Differences** | A modification kit was installed on a standard XE-2100 instrument where samples >48 hours are analyzed. This modification kit includes software and hardware changes and includes a modified reagent, Cellsheath (C). In this modification, the RBC/PLT dilution process will now be diluted using the Cellsheath (C) reagent after being warmed past 20°C. Software and hardware modifications include changes to the instrument's tubing and modification of the heating block. This only impacts the RBC/PLT dilution step. The WBC and HGB parameters are not impacted. This modification kit was not a change due to recall or | A modification kit was installed on a standard XS-1000i instrument where samples >48 hours are analyzed. This modification kit includes software and hardware changes and includes a modified reagent, Cellsheath (C). In this modification, the RBC/PLT dilution process will now be diluted using the Cellsheath (C) reagent after being warmed past 20°C. Software and hardware modifications include changes to the instrument's tubing and modification of the heating block. This only impacts the RBC/PLT dilution step. The WBC and HGB parameters are not impacted. This modification kit was not a change due to recall or corrective action, labeling change, technology or performance change or materials | There is no difference in the modification kit. |

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| | corrective action, labeling change, technology or performance change or materials change. | change. | |
| **Specimen Type** | Random whole blood samples | Random whole blood samples. | Both systems use the same specimen types. |
| **Throughput** | Approximately 113-150 samples/hour depending on the mode used. | Approximately 60 samples/hour depending on the mode used. | There is a difference in the number of samples/hour. |
| **Equivalency Data:** | Performance was established in XE-2100DC 510(k) submission (K051459). | Performance of the XS-1000iC is the same as the XE-2100DC. Comparison of the XS-1000iC to the XE-2100DC demonstrated substantial equivalence. | Performance was substantial equivalence. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Sysmex America, Inc.
C/O Nina Gamperling
One Nelson C. White Parkway
Mundelein, Illinois 60060

AUG 29 2008

Re: k081610
Trade/Device Name: Sysmex Model XS-1000iC Automated Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Hematology Analyzer
Regulatory Class: Class II
Product Code: GKZ
Dated: August 13, 2008
Received: August 15, 2008

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 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D.
Acting Division 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

510(k) Number (if known): K081610

Device Name: Sysmex® XS-1000iC, Automated Hematology Analyzer

Indications For Use: The Sysmex® XS-1000iC is an automated hematology analyzer for *in vitro* diagnostic use in clinical laboratories and reference laboratories. The XS-1000iC will extend MCV stability to 48 hours.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K081610

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)