**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
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October 12, 2015

Sysmex America, Inc.
Peter Shearstone
VP, RA/QA/Clinical and Medical Affairs
577 Aptakisic Road
Lincolnshire, IL 60069

Re: K143577
Trade/Device Name: Sysmex XW-100™, XW QC CHECK
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ, JPK
Dated: September 24, 2015
Received: September 28, 2015

Dear Mr. Shearstone:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
k143577

Device Name
Sysmex XW-100
XW QC CHECK

Indications for Use *(Describe)*
The Sysmex XW-100™ is a quantitative automated hematology analyzer intended for in vitro diagnostic point of care use to classify and enumerate the following parameters for venous whole blood anticoagulated with K2/K3 EDTA: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, NEUT#, RDW-SD, RDW-CV, and MPV. It is not for use in diagnosing or monitoring oncology patients, children under the age of 2, or for chronically or critically ill patients.

XW QC CHECK is a stabilized whole blood matrix designed for statistical process control of the Sysmex XW-100 automated hematology analyzer. It is not intended for calibration of the analyzer. Assayed parameters include WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, NEUT#, RDW-SD, RDW-CV, and MPV.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The 510(k) summary for the Sysmex XW-100 Automated Hematology Analyzer instrument is presented in Table 5.1, and the similarities and differences between the Sysmex XW-100 and predicate pocH-100*i* devices are provided in Table 5.2.

| **Table 5.1** | **Sysmex XW-100 Automated Hematology Analyzer 510(k) Summary** |
|---|---|
| 1. Submitted by | Sysmex America, Inc.<br>577 Aptakisic Rd<br>Lincolnshire, IL 60069<br>Phone: 224.543.9514<br>Fax: 224.543.4699<br>Contact person: Peter Shearstone<br>Date prepared: December 16, 2014 |
| 2. Name of device | Trade or proprietary name: Sysmex XW-100™<br>Common name: XW-100 Automated Hematology Analyzer<br>Classification name: Automated Differential Cell Counter<br>Regulation number: 21 CFR 864.5220<br>Classification: Class 2<br>Product Code: GKZ |
| 3. Predicate device | Sysmex pocH-100*i* ™ Automated Hematology Analyzer |
| 4. Device description | The XW-100 is an electrical resistance type blood cell counter. This technology may be variously referred to as direct current (DC) or impedance. The analyzer uses a human whole blood specimen and produces results for 17 hematology parameters, including the basic complete blood count (CBC), 3 part white blood cell (WBC) differential, and commonly used CBC indices. The analyzer uses DC with hydrodynamic focusing for all parameters except hemoglobin, which is measured photometrically. The patient sample is aspirated, measured, diluted with diluent (and Lyse for WBC measurement), then fed into a transducer chamber by means of a hydrodynamic focusing nozzle. The transducer chamber has a minute hole, or aperture. Electrodes are mounted on both sides of the aperture chamber, through which flows the DC. Blood cells suspended in the diluted sample are injected through the aperture by the hydrodynamic focusing nozzle. The hydrodynamic focusing nozzle is positioned in front of the aperture and in line with the aperture's center. This method improves cell counting accuracy because all blood cells are separated from each other and can only pass through the aperture in 1 direction, 1 at a time. When a cell passes through the aperture, it causes a change in the DC resistance that is directly proportional to its size. These resistance changes are captured as electric pulses. The various blood cell counts are calculated by counting the pulses that occur in each cell size category. The analyzer then determines blood cell |

| **Table 5.1** | **Sysmex XW-100 Automated Hematology Analyzer 510(k) Summary** |
|---|---|
| | volume and identifies rare and pathological cells by creating and analyzing histograms of the various cell populations using their respective pulse heights. Hemoglobin is measured photometrically using a noncyanide methodology, which reduces the presence of hazardous materials in the analyzer waste stream. The quality controls that are used with the XW-100 Automated Hematology Analyzer comprise XW QC CHECK, which contains stabilized red blood cell component(s), stabilized WBC component(s), and stabilized platelet component(s) in a preserving medium. XW QC CHECK components are packaged in glass vials with screw caps containing 2 mL. The vials are packaged in a welled vacuum-formed clamshell container. XW QC CHECK is stored at room temperature (15°C-25°C or 59°F-77°F). |
| 5. Substantial equivalence-similarities and differences | Table 5.2 compares the Sysmex XW-100 with the Sysmex pocH-100*i* automated hematology |
| 6. Clinical performance data | Studies were performed to evaluate the equivalency of the Sysmex XW-100 in the point-of-care (POC) setting with the Sysmex pocH-100*i* automated hematology analyzer. Results indicated equivalent performance.<br>Open-vial stability, closed-vial stability, and precision performance studies were conducted to establish performance of XW QC CHECK; all testing showed that XW QC CHECK met clinical performance acceptability criteria and demonstrated stability for the shelf-life claimed. |
| 7. Conclusions | The performance data demonstrated substantial equivalence to the predicate device. |

## Sysmex XW QC CHECK

The 510(k) summary for the control material, XW QC CHECK, is presented in Table 5.3, and the similarities and differences between the XW-QC CHECK and predicate Para Check control material are provided in Table 5.4.

| **Table 5.3 XW QC CHECK** | |
|---|---|
| 1. Submitted by | Sysmex America, Inc.<br>577 Aptakisic Rd<br>Lincolnshire, IL 60069<br>Telephone: 224.543.9514<br>Fax: 224.543.4699<br>Contact person: Peter Shearstone<br>Date prepared: December 16, 2014 |
| 2. Name of device | Trade or proprietary name: XW QC CHECK<br>Common Name: XW Quality Controls<br>Classification Name: Hematology quality control mixture (864.8625)<br>Product Code: JPK |
| 3. Predicate device | Para® Check (K852992) |
| 4. Device description | XW QC CHECK is an *in vitro* diagnostic product that contains the following: stabilized red blood cell component(s), stabilized white blood cell component(s), and stabilized platelet component(s) in a preserving medium. The product is packaged in glass vials with screw caps containing 2 mL. The vials will be packaged in a welled vacuum-formed clamshell container. The product is stored at (15°C-25°C or 59°F-77°F) subsequent to shipment. |
| 5. Substantial equivalence-similarities and differences | Table 5.4 compares XW QC CHECK with the Para® Check. |
| 6. Clinical performance data | Open-vial stability, closed-vial stability, and precision performance studies were conducted to establish performance of XW QC CHECK. All testing showed that XW QC CHECK met clinical performance acceptability criteria and demonstrated stability for the shelf-life claimed. |
| 7. Conclusions | The performance data demonstrated substantial equivalence to the predicate device. |