November 8, 2022

Sysmex America, INC.
Yvonne Doswell
Senior Scientist, Regulatory Affairs
577 Aptakisic Road
Lincolnshire, Illinois 60069-4325

Re: K210346
Trade/Device Name: Sysmex XW-100 Automated Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: June 20, 2022
Received: June 21, 2022

Dear Yvonne Doswell:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Min Wu -S

Min Wu
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
XW-100 Automated Hematology Analyzer for CLIA Waived Use

Indications for Use *(Describe)*
The XW-100 Automated Hematology Analyzer (XW-100) is a quantitative automated hematology analyzer intended for in vitro diagnostic use to classify and enumerate the following parameters for venous whole blood anticoagulated with K2/K3 EDTA: WBC, RBC, HGB, HCT, MCV, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, and NEUT#. It is not for use in diagnosing or monitoring patients with primary or secondary chronic hematologic diseases/ disorders, oncology patients, critically ill patients, or children under the age of 2.

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.

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510(K) SUMMARY

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:_____

Submitter's name, address, telephone number, a contact person, and date the summary was prepared:

Submitter's Name:	Yvonne Doswell
Submitter's Address:	577 Aptakisic Road Lincolnshire, IL 60069
Submitter's Telephone:	224-543-9708
Submitter's Email:	Doswelly@sysmex.com

Date 510(k) Prepared:	09/29/2022

Name of the device, including the trade or proprietary name, the common or usual name, and the classification name:

Proprietary Name:	XW-100 Automated Hematology Analyzer for CLIA Waived Use
Common Name:	Automated Hematology Analyzer
Regulation Description:	Automated Differential Cell Counter
Regulation Section:	21 CFR 864.5220
Device Class:	2
Product Code:	GKZ

Predicate Device/510(k):

XW-100 Automated Hematology Analyzer for CLIA Waived Use K172604, dual submission CLIA Waiver by Application CW170012

INTENDED USE/INDICATIONS FOR USE

The XW-100 Automated Hematology Analyzer (XW-100) is a quantitative automated hematology analyzer intended for in vitro diagnostic use to classify and enumerate the following parameters for venous whole blood anticoagulated with K2/K3 EDTA: WBC, RBC, HGB, HCT, MCV, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, and NEUT#. It is not for use in diagnosing or monitoring patients with primary or secondary chronic hematologic diseases/disorders, oncology patients, critically ill patients, or children under the age of 2.

Special Conditions for Use Statement(s):

The XW-100 is intended to be used by operators with a minimum of an earned high school diploma or equivalent.

DEVICE DESCRIPTION

The XW-100 Automated Hematology Analyzer for CLIA Waived Use 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 12 hematology parameters, including the basic complete blood count (CBC), 3 part white blood cell (WBC) differential, and MCV.

Principles of Operation

The XW-100 uses direct current 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 one direction, one at a time. When a cell passes through the aperture, it causes a change in the direct current 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 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.

Quality Controls

The quality controls that are used with the XW-100 Automated Hematology Analyzer for CLIA Waived Use 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).

SUMMARY OF SUBSTANTIAL EQUIVALENCE

The proposed modified device, XW-100 Automated Hematology Analyzer for CLIA Waived Use has the same intended use, labeling, and fundamental scientific technology as the predicate device, the XW-100 Automated Analyzer for CLIA Waived Use.

Comparison to the Predicate Device:

Similarities		
Item	**Predicate Device**	**Modified Device**
510(k) Number	K172604	N/A
Device Name	XW-100 Automated Hematology Analyzer for CLIA Waived Use	Same
Intended Use	The XW-100 Automated Hematology Analyzer (XW-100) is a quantitative automated hematology analyzer intended for in vitro diagnostic CLIA waived use to classify and enumerate the following parameters for venous whole blood anticoagulated with K2/K3 EDTA: WBC, RBC, HGB, HCT, MCV, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, and NEUT#. It is not for use in diagnosing or monitoring patients with primary or secondary chronic hematologic diseases/disorders, oncology patients, critically ill patients, or children under the age of 2.	Same
Test Principle	Impedance technology (direct current detection) with hydrodynamic focusing for all parameters except hemoglobin, which is measured photometrically.	Same
Measuring Channel	Single hydrodynamic focused impedance chamber	Same
Sample Type	Anticoagulated (K_2EDTA or K_3EDTA) venous whole blood	Same
Sample aspiration volume	15 µL	Same

Similarities		
Item	**Predicate Device**	**Modified Device**
Analysis Reagents	XW Pack L (lyse) XW Pack D (diluent)	Same
System Throughput	20 cycles per hour	Same
Test System Dimensions	Width: 7 inches Height: 14 inches Depth: 18 inches	Same
Mode of Operation	Whole blood mode	Same
Calibration and Quality Control	XW QC CHECK (k143577) SCS™-1000 calibrator (k943268)	Same
Differences		
Item	**Predicate Device**	**Modified Device**
Software	Version 1.03	Version 1.14

Differences:
There is no difference between the XW-100 Automated Hematology Analyzer for CLIA Waived Use and the modified device aside from a software update from Version 1.03 to Version 1.14.

CONCLUSION:
The proposed software update was implemented in accordance to design controls and risk management. The risk analysis and well-established methods of verification and validation activities conducted, demonstrate that the XW-100 Automated Hematology Analyzer for CLIA Waived Use with the proposed software version 1.14 is as safe and effective as the predicate device. The results of the design control activities demonstrate that the device is substantially equivalent to the predicate device, XW-100 Automated Hematology Analyzer for CLIA Waived Use (K172604/CW170012).