DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 22, 2016

Sysmex America, Inc.
Ms. Sharita Brooks
Sr. Manager, Regulatory Affairs
577 Aptakistic Road
Lincolnshire, IL 60069

Re: K160538
Trade/Device Name: Sysmex® XN-L Automated Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: December 12, 2016
Received: December 13, 2016

Dear Ms. Brooks:

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 Parts 801 and 809); 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,

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)*
K160538

Device Name
Sysmex ® XN-L Automated Hematology Analyzer

Indications for Use *(Describe)*
The Sysmex XN-L analyzer is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patient populations found in clinical laboratories. The XN-L analyzer classifies and enumerates the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF# parameters in cerebrospinal, peritoneal, pleural, and synovial fluids. Whole blood should be collected in K2 or K3EDTA anticoagulant and peritoneal, pleural, and synovial fluids in K2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.

The performance of this device has not been established in pediatric patients under the age of 2 years.

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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5. 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: k160538.

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

Submitter's Name: Sysmex America, Inc.

Submitter's Address: 577 Aptakistic Road
Lincolnshire, IL 60069

Submitter's Telephone: (224) 543-9618

Submitter's FAX: (224) 543-9699

Submitter's Contact: Sharita Brooks

Date 510(k) Summary Prepared: February 25, 2016

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

Proprietary Name: Sysmex® XN-L Automated Hematology Analyzer

Common Name: Automated Hematology Analyzer

Regulation Description: Automated Differential Cell Counter

Regulation Section: 21 CFR 864.5220

Device Class: 2

Product Code: GKZ

Related Items:

Product Code: 81GIF
CELLPACK® DCL (Diluent)
CELLPACK® DST (Diluent)
CELLPACK® DFL (Diluent)

Product Code: 81GGK
SULFOLYSER® (Lyse)
Lysercell™ WDF (Lyse)

Product Code: 81KJK
Fluorocell™ WDF (Dye)
Fluorocell™ RET (Dye)

Product Code: 81KSA
XN CAL™ (Calibrator)

Product Code: 81JPK
XN CHECK™ (Control)
XN CHECK™ BF (Control)
XN-L CHECK™ (Control)

Product Code: 81JCB
CELLCLEAN™ AUTO

Predicate Device and 510(k) number: Sysmex XN-Series (XN-10, XN-20) Automated Hematology Analyzer, K112605

Description of the Device:

The Sysmex XN-L analyzer is a quantitative multi-parameter automated hematology analyzer intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XN-L analyzer classifies and enumerates whole blood and body fluid parameters by means of electrical impedance, laser light scattering, and fluorescent labeling. Tests are performed on venous and capillary whole blood samples collected in K_2 or K_3 EDTA anticoagulant and body fluids (peritoneal, pleural and synovial) collected in K_2EDTA anticoagulant and cerebrospinal fluid that is not collected in anticoagulant. The instrument consists of two principal units: (1) Main Unit which will aspirate, dilute, mix, and analyze whole blood and body fluid samples and (2) Pneumatic Unit which supplies pressure and vacuum to the analyzer. The XN-L analyzer performs analysis using the following methods: DC Sheath Flow Detection Method, Flow Cytometry Methods using a Semiconductor Laser, and SLS- hemoglobin Method. Particle characterization and identification is based on detection of forward scatter, fluorescence, and adaptive cluster analysis. The XN-L analyzer automatically classifies cells from whole blood and body fluids and carries out all processes automatically from aspiration of the sample to outputting the results.

The XN-L has an external monitor with touch screen capability that is used to operate the instrument and process data from the Main Unit. The monitor also allows operator interfacing with the instrument by use of a panel keyboard.

Statement of Intended Use:

The Sysmex XN-L analyzer is a quantitative multi-parameter automated hematology analyzer intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XN-L analyzer classifies and enumerates the following parameters in venous and capillary whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF# parameters in cerebrospinal, peritoneal, pleural, and synovial fluids. Whole blood should be collected in K_2 or K_3EDTA anticoagulant and peritoneal, pleural, and synovial fluids in K_2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.

The performance of this device has not been established in pediatric patients under the age of 2 years.

Summary of Substantial Equivalence:

Table 5-1 compares the Sysmex XN-L Automated Hematology analyzer with the XN-Series (XN-10, XN-20) Automated Hematology analyzer.

Table 5-1: Comparison of the Predicate XN-10 and the Proposed XN-L Automated Hematology Analyzers

Item	Predicate Analyzer XN-Series (XN-10)[a] K112605	Proposed Analyzer XN-L
Similarities		
Intended Use	The XN-Series modules (XN-10, XN-20) are quantitative multi-parameter automated hematology analyzers intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XN-Series modules classify and enumerate the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC%/#, RET%/#, IPF, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF parameters in cerebrospinal fluid (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Whole blood should be collected in K_2 or K_3EDTA anticoagulant and, Serous and Synovial fluids in K_2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.	The Sysmex® XN-L analyzer is a quantitative multi-parameter automated hematology analyzer intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XN-L analyzer classifies and enumerates the following parameters in venous and capillary whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF# parameters in CSF, peritoneal, pleural and synovial fluids. Whole blood should be collected in K_2 or K_3 EDTA anticoagulant and peritoneal, pleural and synovial fluids in K_2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended. The performance of this device has not been established in pediatric patients under the age of 2 years.
Specimen Type	Whole Blood and Body Fluids (CSF and Peritoneal, Pleural, Synovial Fluids)	SAME
Test Principle	Performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS-hemoglobin method.	SAME

Parameters	Whole Blood Mode: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, IG%/#, RET-He# Body Fluid Mode: WBC-BF, RBC-BF, MN%/#, PMN%/#, TC-BF#	SAME

Item	Predicate Analyzer XN-Series (XN-10)[a] K112605	Proposed Analyzer XN-L
Reagents	K112605 CELLPACK® DCL (Diluent) CELLPACK® DFL (Diluent) Lysercell™ WDF (Lyse) Fluorocell™ WDF (Stain) Fluorocell™ RET (Stain) SULFOLYSER® (Lyse)	SAME
Analysis Modes	Sampler Analysis Mode (rack autoloader) Whole Blood Mode Manual Analysis Mode Whole Blood Mode LWBC Analysis Mode Pre-Dilute Analysis Mode Body Fluid Mode	SAME
Sample Aspiration/ Fluidic Pathway	Single Pathway	SAME
Measuring Channels	RBC/PLT, HGB, RET, WDF	SAME
Controls/ Calibrators/ Linearity Material	Whole Blood XN CHECK™ 3 Levels (K120742) XN CAL™ (K120745) Body Fluid XN CHECK™ BF 2 Levels (K120744) Whole Blood Linearity Range Check X III (K960557) Retic Chex (K000115)	SAME
Cleaning Detergent	CELLCLEAN AUTO™	SAME
Software/ Hardware	Rules based rerun/reflex	SAME
	Differences	
Parameters	PLT (PLT-F), NRBC%/#, IPF	Not Available
Reagents	K112605 Lysercell™ WNR (Lyse) Fluorocell™ WNR (Stain) Fluorocell™ PLT (Stain)	 Not Available Not Available Not Available
Measuring Channels	WNR, PLT-F	Not Available

Item	Predicate Analyzer XN-Series (XN-10)[a] K112605	Proposed Analyzer XN-L
Controls/ Calibrators	XN CAL™ PF – (K120747) Not Available	Not Available XN-L CHECK™ [b]
Throughput	Whole Blood Mode 100 samples/hour maximum depending on mode used. Body Fluid Mode 40 samples/hour maximum	Whole Blood Mode 60 samples/hour maximum depending on mode used. Body Fluid Mode 30 samples/hour maximum
Sample Aspiration Volumes	Sampler Mode - 88 µL Manual (Closed Cap) Mode - 88 µL Manual (Open Cap) Mode - 88 µL Dilution Mode - 70 µL Body Fluid Mode - 88 µL	Sampler Mode - 25 µL Manual (Closed Cap) Mode - 25 µL Manual (Open Cap) Mode - 25 µL Dilution Mode - 70 µL Body Fluid Mode - 70 µL

[a] Intended use for the predicate analyzer was cleared in submission K112605. All information listed for the predicate analyzer refers to the XN-10 module.
[b] Control material specific for the XN-L analyzer.

The XN-L analyzer's Indications for Use statement is similar to the predicate device with minor variation. The XN-L analyzer also has similar technological characteristics as the predicate device with minor variation. Both devices measure similar parameters and utilize most of the same reagents, controls, calibrators, and cleaning detergent. The data collection software functionality, communication method with data management software functionality, monitor software, connectivity, and communication are similar to the predicate device with minor variation.

The XN-L analyzer differs from the predicate with a slower throughput and smaller sample aspiration volumes, fewer measuring channels, and fewer parameters measured, it is very similar in all other electronic and technological characteristics related to automated hematology measurements of the predicate device to assure equivalence. In addition, XN-L CHECK™ is a control material which is specific for the XN-L analyzer. The XN-L CHECK™ or the XN CHECK™ may be used with the XN-L analyzer. Performance data are provided to support this. The results of all performance testing demonstrate substantial equivalence.

Summary of Performance Testing:

Clinical testing was conducted on the XN-L analyzer to show equivalent performance to the XN-Series analyzers. Testing included:

- Whole Blood Analysis
  - Accuracy Evaluation
  - Precision Evaluation: Reproducibility
  - Precision Evaluation: Repeatability
  - Linearity Evaluation

- Carryover Evaluation
- Stability Evaluation
- Verification of Reference Intervals
- Limits of Blank, Detection, and Quantitation

- Body Fluid Analysis
  - Accuracy Evaluation
  - Precision Evaluation: Reproducibility
  - Precision Evaluation: Repeatability
  - Linearity Evaluation
  - Carryover Evaluation
  - Stability Evaluation
  - Limits of Blank, Detection, and Quantitation

Evaluation of the performance characteristics establishes that the performance, functionality, and reliability of the XN-L analyzer are substantially equivalent to the predicate device. The evaluation included accuracy, precision, linearity, carryover, stability, and Limits of Blank, Detection and Quantitation on whole blood and body fluid and verification of reference intervals on whole blood.

Conclusions:

The XN-L Automated Hematology analyzer and its predicate device, XN-Series modules (XN-10, XN-20) Automated Hematology analyzers (K112605), have similar Indications for Use, fundamental technology, principles of operation, and comparable performance characteristics. The modifications consist of a smaller analyzer with a slower throughput and smaller sample aspiration volumes.

Performance, verification, and validation testing were conducted to characterize the performance of the XN-L analyzer and the predetermined acceptance criteria were met. Results of this testing have documented that the XN-L analyzer is substantially equivalent to the XN-Series analyzers and is suitable for the labeled indication for use. The XN-L analyzer and the predicate device do not raise any questions regarding safety and effectiveness.