DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 5, 2014

Sysmex America, Inc.
c/o Ms. Sharita Brooks
Manager Clinical Affairs
577 Aptakisic Road
Lincolnshire, IL. 60069

Re: k141681
Trade/Device Name: Sysmex® XN-Series (XN-11, XN-21) Automated Hematology Analyzers
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: October 30, 2014
Received: October 31, 2014

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 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,

Maria M. Chan -S

Maria M. Chan, Ph.D.
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)*
k141681

Device Name
XN-Series (XN-11, XN-21) Automated Hematology Analyzers

Indications for Use *(Describe)*
The XN-Series modules (XN-11, XN-21) are quantitative multi-parameter automated hematology analyzers intended for in vitro diagnostic use in screening patient populations found in clinical and reference 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 body fluids (peritoneal, pleural and synovial). 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.

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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005 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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: _____.

1. Submitted by:	Sysmex America, Inc. 577 Aptakisic Road Lincolnshire, IL. 60069 Phone: (224) 543-9618; FAX: (224) 543-4699 Contact person: Sharita Brooks Date prepared: June 19, 2014
2. Name of Device:	Trade or proprietary name: Sysmex® XN-Series (XN-11, XN-21) Common name: Automated Hematology Analyzer Classification name: Automated Differential Cell Counter 21 CFR 864.5220 is a Class II device. Product Code: **GKZ** **Related Items:** **Product Code: 81 GIF** CELLPACK® DCL (Diluent) – K112605 CELLPACK™ DFL (Diluent) – K112065 CELLSHEATH(C)™ (Diluent) – K051459 **Product Code: 81 GGK** Lysercell™ WNR (Lyse) – K112605 Lysercell™ WDF (Lyse) – K112605 Lysercell™ WPC (Lyse) – K112605 **Product Code: 81 KJK** Fluorocell™ WNR (Stain) – K112605 Fluorocell™ WDF (Stain) – K112605 Fluorocell™ RET (Stain) – K112065 Fluorocell™ PLT (Stain) – K112605 Fluorocell™ WPC (Stain) – K112605 **Product Code: 81 KSA** XN CAL (Calibrator) – K120745 XN CAL PF (Calibrator) – K120747 **Product Code: 81 JPK** XN CHECK (Control) – K120742 XN CHECK BF (Control) – K120744 **Analyzer Components** SA-10 (Auto Sampler for single module) SA-20 (Auto Sampler for two modules) IPU (Information Processing Unit)
3. Predicate Device:	Sysmex® XE-5000Automated Hematology Analyzer

4. Device Description:	The Sysmex® XN-Series modules (XN-11, XN-21) are multi-parameter hematology analyzers intended to perform tests on whole blood samples collected in K_2 or K_3EDTA anticoagulant and body fluids (pleural, peritoneal and synovial) collected in K_2 anticoagulant. The XN-Series modules (XN-11, XN-21) are part of the family of XN-Series devices (K112605) cleared Oct 19, 2012 with modifications to stabilize the HCT/MCV parameters to within +8% at room temperature (18-26°C) for 24 hours and refrigerated temperature (2-8°C) for 48 hours for commercial and reference laboratories. The difference between the XN-11 and XN-21 is the presence of the WPC Channel in the XN-21. The instrument consists of four principal units: (1) Two Main Units (XN-11, XN-21) which aspirate, dilute, mix, and analyze blood and body fluid samples; (2) Two Auto Sampler Units (SA-10 for a single module, or SA-20 for two modules) which supply 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; (4) Pneumatic Unit which supplies pressure and vacuum from the Main Unit. The XN-Series analyzers perform analysis using the following methods: Sheath Flow DC Detection Method, and Flow Cytometry Methods using a Semiconductor Laser. Particle characterization and identification is based on detection of forward scatter, fluorescence and adaptive cluster analysis. The XN-Series analyzers automatically classify cells from whole blood and body fluids and carry out all processes automatically from aspiration of the sample to outputting the results. The body fluid analysis mode of the XN-Series analyzers uses the 4DIFF scattergram & the RBC distribution obtained from a specialized analysis sequence to calculate & display the WBC (WBC-BF) counts, mononuclear cell (MN) / polymorphonuclear cell (PMN) counts & percentages, Total Count (TC-BF) & RBC (RBC-BF) counts found in the body fluid. Analysis results and graphics are displayed on the IPU screen. They can be printed on any of the available printers or transmitted to a Host computer.
5. Intended Use:	The XN-Series modules (XN-11, XN-21) are quantitative multi-parameter automated hematology analyzers intended for *in vitro* diagnostic use in screening patient populations found in clinical and reference 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 body fluids (peritoneal, pleural and synovial). 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.
6. Substantial equivalence-similarities and differences	The following table compares the XN-Series modules (XN-11, XN-21) Automated Hematology analyzers with the XE-5000 Automated Hematology analyzer.
7. Clinical Performance Data:	Studies were performed to evaluate the equivalency of the XN-Series Automated Hematology analyzers (Modules XN-11, XN-21) to the XE-5000 Automated Hematology analyzer. Results indicated equivalent performance.
8. Conclusions:	The performance data demonstrated substantial equivalence.

Table 1: Substantial Equivalence – Similarities and Differences to the XN-Series Automated Hematology analyzers (Modules XN-11, XN-21) and XE-5000 Automated Hematology analyzer.

Item	Predicate XE-5000 (K071967) 20-Nov-07	Device XN-Series (XN-11, XN-21)
Intended Use	Sysmex® XE-5000 is an automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XE-5000 classifies and enumerates the same parameters as the XE-2100 using whole blood as described below, cord blood for HPC and has a body fluid mode for body fluids. The Body Fluid mode analyzes WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF in body fluids (cerebrospinal fluids (CSF), serous fluids, and synovial fluids with EDTA, as needed). WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT% / #, LYMPH% / #, MONO% / #, EO% / #, BASO% / #, NRBC% / #, RDW-SD, RDW-CV, MPV, RET% / #, IRF, IG% / #, RET-He, IPF, HPC WBC-BF, RBC-BF, MN% / #, PMN%/ #, TC-BF#.	The XN-Series modules (XN-11, XN-21) are quantitative multi-parameter automated hematology analyzers intended for *in vitro* diagnostic use in screening patient populations found in clinical and reference 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 body fluids (peritoneal, pleural and synovial). 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.
Equivalency Data	Proven performance in FDA submission	Data consisting of Accuracy, Precision, Linearity and Carryover were collected to show performance to the manufacturer's specification for the Whole Blood and Body Fluid mode. This analysis supports the claim that the XN-Series analyzers are substantially equivalent to the XE-5000.
Similarities		
Specimen Type	Whole Blood and Body Fluids (Serous, Synovial)	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%/#, NRBC%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, IG%/#, RET-He, IPF. **Body Fluid Mode:** WBC-BF, RBC-BF, MN%/#, PMN%/#, TC-BF#	SAME

Reagents	SULFOLYSER (Lyse)	SAME
Modes of Operation	Sampler Analysis Mode Manual Closed Analysis Mode Body Fluid Analysis Mode	SAME
Measuring Channels	RBC/PLT RET	SAME
Differences		
Item	**Predicate XE-5000 (K071967) 20-Nov-07**	**Device XN-Series (XN-11, XN-21)**
Specimen type	Body Fluid – CSF Umbilical Cord Blood	Not Available Not Available
Test Principal	RF/DC detection method	Not Available
Controls & Calibrators	**Whole Blood** e-Check (XE) – 3 Levels X CAL (XE Calibrator) Not Available **Body Fluid** Not Available	**Whole Blood** XN CHECK – 3 Levels XN CAL (XN-Series Calibrator) XN CAL PF (Platelet F Calibrator) **Body Fluid** XN CHECK BF – 2 Levels
IPU	Single Module connect	Multi-Module connect
Modes of Operation	Manual Open Cap Analysis Mode (Operator presents sample to aspiration needle) Capillary Analysis Mode Dilute sample 1:5 Not Available	Manual Open Cap Analysis Mode (Sample placed in tube holder position) Pre-dilute Analysis Mode Dilute sample 1:7 Low WBC Mode (LWBC)
Parameters	HPC	Not Available
Sample Aspiration /Fluidic Pathway	Two pathways	Single pathway
Software/Hardware	Not Available	Rules-based rerun/reflex
Throughput	**Whole Blood** Approximately 113-150 depending on mode used. **Body Fluid** 38 samples/hour	**Whole Blood** 100 samples/hour maximum depending on mode used. **Body Fluid** 40 samples/hour maximum
Measuring Channels (see Section 11 for detailed information on these channels)	WBC/BASO, DIFF, NRBC IMI Not Available	WNR,WDF WPC (Not available on XN-11) PLT-F
Reagents	CELLPACK® (Diluent) CELLSHEATH™ (Diluent) **NOT AVAILABLE** STROMATOLYSER™-FB (Lyse) STROMATOLYSER™-4DL (Lyse) STROMATOLYSER™-4DS (Stain) STROMATOLYSER™-NR (Diluent) STROMATOLYSER™-NR (Stain) RET-SEARCH II (Diluent) RET-SEARCH II (Stain) STROMATOLYSER™- IM (Lyse)	CELLPACK® DCL (Diluent) CELLPACK™ DFL (Diluent) CELLSHEATH(C)™ (Diluent) Lysercell™ WNR (Lyse) Lysercell™ WDF (Lyse) Lysercell™ WPC* (Lyse) Fluorocell™ WNR (Stain) Fluorocell™ WDF (Stain) Fluorocell™ RET (Stain) Fluorocell™ PLT (Stain) Fluorocell™ WPC* (Stain) *Not used on XN-11 module.

Sample Aspiration Volume	Sampler Mode – 200µL Manual (Closed Cap) Mode - 200µL Manual (Open Cap) Mode - 130µL Capillary Mode - 130µL Body Fluid Mode - 130µL	Sampler Mode – 88µL Manual (Closed Cap) Mode - 88µL Manual (Open Cap) Mode - 88µL Dilution Mode - 70µL Body Fluid Mode - 88µL