November 5, 2018

Athelas Inc.
Tanay Tandon
CEO
10209 Danube Drive
Cupertino, CA, 95014

Re: K181288
Trade/Device Name: Athelas One
Regulation Number: 21 CFR 864.5520
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: May 9, 2018
Received: May 16, 2018

Dear Tanay Tandon:

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 and Part 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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181288

Device Name
Athelas One

Indications for Use *(Describe)*
Athelas One is indicated for use for quantitative determination of white blood cells (WBC) and Neutrophil percentages (NEUT%) in capillary or K2EDTA venous whole blood. The Athelas One system is for In Vitro Diagnostic use only. The Athelas One is only to be used with Athelas One Test Strips. The Athelas One is indicated for use in clinical laboratories and for point of care settings. The Athelas One is only indicated for use in adult populations (aged 21 and older).

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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Section 5 - 510(k) Summary

Date Prepared:
Sept. 15th, 2018

Submitter:
Tanay Tandon (Athelas) and Guy Beauparlant (TPIReg)
Company: Athelas Inc.
Address: 10209 Danube Dr. Cupertino, CA 95014
Email Address: tanay@athelas.com

Proprietary Trade name:
Athelas One

Common name:
Automated differential cell counter.

Classification name:
Automated differential cell counter (21 CFR 864.5220, Product Code GKZ)

Indicated use:
Athelas One is indicated for use for quantitative determination of white blood cells (WBC) and neutrophil percentages (NEUT%) in capillary or K2EDTA venous whole blood. The Athelas One system is for In Vitro Diagnostic use only. The Athelas One is only to be used with Athelas One Test Strips. The Athelas One is indicated for use in clinical laboratories and for point of care settings. The Athelas One is only indicated for use in adult populations (aged 21 and older).

Substantial Equivalence:
Sysmex XE-5000, Automated Haematology Analyzer (K071967)

Comparison with predicate:

Similarities		
Item	Device: Athelas One	Predicate: XE-5000
Intended Use	Athelas One is indicated for use for quantitative determination of white blood cells (**WBC**) and Neutrophil percentages (**NEUT%**) in capillary or K2EDTA venous whole blood. The Athelas One system is for In Vitro Diagnostic use only. The Athelas One is only to be used with	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,

	Athelas One Test Strips. The Athelas One is indicated for use in clinical laboratories and for point of care settings. The Athelas One is only indicated for use in adult populations (aged 21 and older).	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#.
Intended use sites	Point of Care, Clinical Laboratory	Clinical laboratory
Specimen Type	Capillary and Venous Whole Blood	Venous Whole Blood, Capillary and CSF

Differences		
Item Name	Athelas One	Predicate: Sysmex XE-5000
Test Principle	A microfluidic test strip channel creates a stained monolayer of white blood cells. Multiple images are taken of the monolayer and the cells are counted and classified by computer vision based image analysis.	Performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS hemoglobin method.
Parameters	WBC, NEUT%	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#
Target Population	Only Adult (21 and older).	Pediatric and Adult
Reagents	Cresyl Violet, Methylene Blue Stain (pre-loaded/coated dry and contained in test strip)	SULFOLYSER
Controls/ Calibrators	Whole Blood: ATH-CHECK (3 level control)	Whole Blood: e-Check (XE) - 3 Levels X CAL (XE Calibrator) Not available Body Fluid: Not available
Modes of Operation	Single mode of operation for both venous and capillary samples	Manual Open Cap Analysis Mode (Operator presents sample to aspiration needle)

		Capillary Analysis Mode Dilute sample 1:5 Not Available
Software/Hardware	Internet connected device for processing results on cloud server.	Processing of results occurs locally on device.
Throughput	Whole Blood 10 samples/hour maximum.	Whole Blood Approximately 113-150 depending on mode used.
Sample Aspiration Volume	3.5 µL	130 - 200 µL depending on mode
Measurement Range	WBC: 1 - 25K/µL	WBC: 0.00 - 440 K/µL
Calibration	Factory calibrated and automatic calibration at the beginning of each test. No manual calibration by end user.	Automatic and manual calibration using e-Check (XE) control material.

Description of Device:

The Athelas One is an automated diagnostic device intended to perform tests on whole blood samples collected in K2EDTA or capillary finger stick samples collected directly into the Athelas One test strip. The system is intended to be placed within the Point of Care, and Clinical Laboratory sites. Athelas One returns WBC and Neut% metrics from the blood sample.

A clinician places a sample on the Athelas One test strip either directly from finger or via pipette from K2EDTA whole blood tube. The Athelas One test strip stains and creates a monolayer of the blood sample within the chamber. The strip is inserted into the test strip slot of the Athelas One device and the device returns results by conducting image analysis of cells present. Result-viewing and device control are conducted through a companion tablet/mobile application.

The precision/bias goals of the device are provided below:

Target Evaluation Criteria:

WBC Precision: 7.5% CV above 2K/µL WBC. 0.25 K/µL SD below 2K/µL WBC.
WBC Bias/Error: ±7.5% error above 2K/µL WBC. ±0.25 K/µL error below 2K/µL WBC.

Neutrophil % Precision: 5% SD OR 15% CV (updated based on Sysmex XW-100 Neut% CV criteria).
Neutrophil % Bias: ±10% bias or ±5% Neut% total error (whichever larger).

These targets were chosen based on CLSI clinical precision/bias recommendations for WBC and Neut%. Constant value targets where set to account for asymptotically increasing percent imprecision towards lower concentrations as per the poisson distribution.

Description of Intended Setting:
The Athelas One is designed for use in Point of Care (PoC) and Clinical Laboratory settings. The intended PoC setting is one in which the device is placed in a safe, stationary location only accessible by authorized staff. As per the cybersecurity suggestions, the device should be connected to the internet either via a wired ethernet connection or a protected WPA 802.11n network. The network of the PoC setting should be placed behind a firewall that strictly regulates access to only those services that need it.

In the intended setting, the Athelas One is to remain in a stationary location free from movements and any potential vibrations. Operators are not to move the device from one location to another. The device should be placed in an environment with a temperature between 68–77° F and the Athelas One test strips should also be stored in a similar setting.

Summary of Technological Characteristics Compared to Predicate Devices:
The Athelas One and Sysmex XE-5000 are both intended for automated analysis of WBC and Neut% values from K2EDTA and Capillary Whole Blood. The Athelas One utilizes a microfluidic chamber and image processing to analyze cells. The Sysmex XE-5000 utilizes aspiration of blood, Hydro Dynamic Focusing (DC Detection), and flow cytometry methods (using a semiconductor laser). In both cases, cells are analyzed and classified based on morphological, granule characterization, and size parameters.

Testing: Both Bench and Clinical testing were conducted to showcase substantial equivalence between the Athelas One and predicate device.

Bench

Within-run Precision/Reproducibility

Within-run Precision Repeatability

Precision studies were performed using K2EDTA whole blood samples around medical decision levels and the upper and lower limit of the analytical measuring range. The study was conducted with nine whole blood samples, three different operators and three different test strip lots. Care was taken to include both normal and abnormal samples.

Three operators and three test strip lots were used in conjunction. Per operator, per lot, ten replicates of each sample were tested and the results were recorded. 90 tests were run per sample, with 810 tests run in total. The mean, standard deviation (SD), and coefficient of variation (CV) were calculated for each sample. All results met the predefined specifications (CV%) for precision (targets shown on below table as well).

WBC Summarized

Sample	Mean Value (K/µL)	N	Repeatability		Between-Lot		Between-Instrument		Between-Operator		Total		Target Evaluation		
			SD (K/µL)	CV (%)	SD (K/µL)	CV (%)	SD (K/µL)	CV (%)	SD (K/µL)	CV (%)	SD (K/µL)	CV (%)	Target Metric	Experiment Value	Target Value
1	2.20	90	0.12	5.62	0.00	0.00	0.00	0.00	0.04	1.70	0.13	5.87	CV	5.87%	7.50%
2	3.75	90	0.20	5.42	0.00	0.00	0.01	0.36	0.02	0.60	0.20	5.46	CV	5.46%	7.50%
3	4.12	90	0.20	4.78	0.00	0.00	0.06	1.43	0.04	1.02	0.21	5.09	CV	5.09%	7.50%
4	5.11	90	0.25	4.96	0.00	0.00	0.14	2.73	0.10	1.87	0.30	5.96	CV	5.96%	7.50%
5	7.89	90	0.33	4.18	0.06	0.78	0.09	1.14	0.15	1.94	0.38	4.82	CV	4.82%	7.50%
6	10.01	90	0.50	5.01	0.00	0.00	0.10	0.98	0.19	1.91	0.55	5.45	CV	5.45%	7.50%
7	14.64	90	0.66	4.51	0.19	1.27	0.00	0.00	0.00	0.00	0.69	4.69	CV	4.69%	7.50%
8	17.52	90	0.70	3.97	0.00	0.00	0.17	0.95	0.26	1.49	0.76	4.34	CV	4.34%	7.50%
9	23.33	90	1.01	4.33	0.77	3.31	0.20	0.87	0.43	1.82	1.36	5.81	CV	5.81%	7.50%

Precision Reproducibility (between run)

Precision/Reproducibility studies were performed on the Athelas One Whole Blood Manual Mode using three levels of ATH-check quality control material (Low, Normal and High). The 20-day study used three sites, with three analyzers (one instrument per site), three lots of test strips, and one lot of quality control materials (all levels). We performed two runs per day and two replicates per run with two operators per site. A total of 80 readings were generated at each site for each level of control (2 runs x 20 days x 2 replicates = 80 readings). As per Agency recommendation results were analyzed using ANOVA analysis and taking into account the nested design of the study.

Low

Low

Overall Summary Table

Measurand	Mean Value	N	Within-Run		Between-Run		Between-Day		Between-Site		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC	2.746	240	0.140	5.097	0.000	0.000	0.060	2.175	0.018	0.673	0.153	5.583
NEUT %	50.781	240	2.680	5.278	1.239	2.440	1.305	2.570	1.197	2.356	3.443	6.780

Medium

Medium

Overall Summary Table

Measurand	Mean Value	N	Within-Run		Between-Run		Between-Day		Between-Site		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC	7.546	240	0.339	4.492	0.112	1.479	0.080	1.062	0.230	3.049	0.432	5.726
NEUT %	49.990	240	3.015	6.030	0.932	1.865	0.833	1.666	0.728	1.457	3.344	6.689

High

High

Overall Summary Table

Measurand	Mean Value	N	Within-Run		Between-Run		Between-Day		Between-Site		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC	15.246	240	0.656	4.300	0.000	0.000	0.460	3.014	0.532	3.491	0.961	6.305
NEUT %	50.823	240	2.967	5.838	0.000	0.000	0.947	1.864	1.139	2.241	3.316	6.525

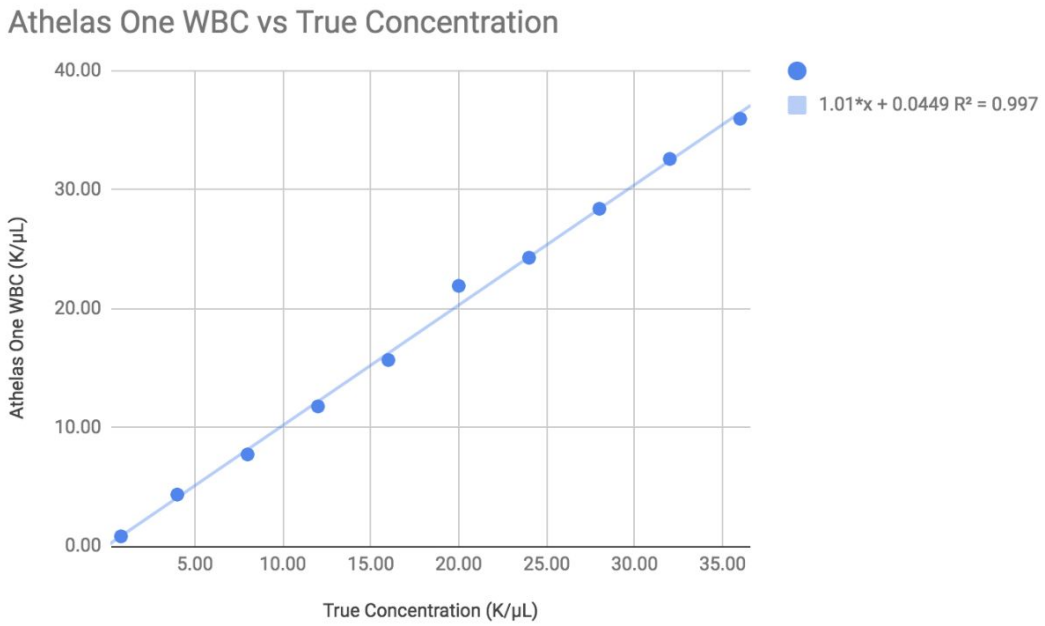
A site by site analysis was also conducted as per Agency recommendation, also falling within evaluation criteria. Overall reproducibility levels were found to meet the acceptance criteria of 7.5% CV for WBC and 5% SD or 15% CV for Neutrophils across all three levels and all sites.

Linearity

10 samples across the reporting range were run in 4 replicates across 4 devices and one test strip lot. The samples were obtained by pooling together one low WBC concentration fresh whole blood sample one high WBC concentration sample in different volumes which is a recommended option in CLSI EP6-A.

The method has been demonstrated to be linear from lower limit to upper limit and within measured allowable max % diff for each interval. The primary analyte (WBC) was analyzed in linearity as per CLSI EP06-A guidance. The CLSI recommended OLS regression of the linearity data is provided below:

Parameter	N	R^2	Slope	Intercept	CVr
WBC	10	0.997	1.013	0.0449	5.08%



Interfering Substances

Interference studies were performed taking sample abnormalities, drugs, metabolites, sample additives and dietary substances into consideration. A list of substances were tested and found naturally occurring in patient samples, or were spiked in whole blood. This list is included is included below (with highest concentration or percentages tested). None of the substances were found to interfere with the measurements of the Athelas One device. This was evaluated through analysis of interferon impact on bias and precision performance. All interferon spiked samples continued to perform within the evaluation criteria.

- Triglyceride Rich Lipoproteins
- Hemolysate
- Protein
- Levodopa
- Methyldopa
- Metronidazole
- Acetylsalicylic Acid
- Phenylbutazone
- Rifampicin
- Cyclosporine

- Acetaminophen
- Heparin
- Ibuprofin
- Bilirubin C
- Bilirubin F
- Reticulocytes
- Platelet Aggregates
- Nucleated Red Blood Cells
- Giant Platelets
- Myelodysplastic Syndrome
- Macrocytic Anemia
- Infectious Mononucleosis
- Bacterial Infections
- Chronic Myeloid Leukemia
- Patients on Chemotherapy
- Patients treated with GCSFs

Reference Intervals

Adult reference intervals for the Athelas One were verified across 120 healthy donors in comparison to pre-established reference intervals for the Sysmex XE-5000 utilizing whole blood samples.

Limit of Blank (LoB) – Whole Blood

The LoB was obtained from 120 total repeated measurements of blank samples analyzed in the sampling modes for whole blood. The mean, SD and LoB were calculated for the analyzer. The LoB for whole blood parameters WBC is zero (0) K/µL.

Limit of Detection (LoD) – Whole Blood

As per Agency recommendation, Limit of Detection was conducted using run as follows:

- 2 test strip lots (60 strips each)
- 2 instruments
- 3 days
- 5 low level samples
- 2 replicates per sample

Test Strip Lot 1 Summarized Data

N	LoB (from LoB section)	c_p	Pooled Standard Deviation (K/µL)	LoD (K/µL)
60	0	1.653	0.033	0.055

Test Strip Lot 2 Summarized Data

N	LoB (from LoB section)	c_p	Pooled Standard Deviation (K/µL)	LoD (K/µL)
60	0	1.653	0.048	0.079

As shown in the Limit of Blank section, the LoB was found to be 0.

The LoD of Lot 1 was 0.055 K/µL while the LoD of Lot 2 was 0.079 K/µL. The maximum LoD of the two lots was established as the final LoD. Hence, the LoD was set to be 0.079 K/µL.

The LoD was found to be 0.079 K/µL which is well below the LoQ of 0.44 K WBC/µL.

Limit of Quantification (LoQ) – Whole Blood

The Limit of Quantification study was designed to estimate the lowest measurement concentration that can be measured on the Athelas One and meet the predefined total error goals. **The study was conducted over two test-strip lots, 1 instrument, 3 days, 3 replicates per sample, and 4 independent low-level whole blood samples.** The samples were distinct whole blood samples acquired from patients in K_2EDTA tubes. The original concentrations were obtained from the predicate analyzer (Sysmex XE-5000). These samples were then diluted to reach an approximate concentration of 0.45 K WBC/µL. The original concentrations, the volume of diluent, and the final concentrations of the samples are shown in the table below.

Sample	WBC Initial (K/µL)	Volume of Sample in Aliquot (µL)	Volume of Diluent in Aliquot (µL)	Final Aliquot Concentration (K/µL)	Final Aliquot Volume (µL)
1	3.97	100	800	0.44	900
2	3.92	100	800	0.44	900
3	4.16	100	800	0.46	900
4	3.13	100	600	0.45	700

The Limit of Quantification of the Athelas One was determined to be **0.44 K WBC/µL** as per CLSI EP17-A2. This is below the lower limit of the Athelas One's reporting range of 1.0K WBC/µL.

Specimen Stability Studies

Whole blood stability - Room temperature vs Refrigerated temperature

Whole blood stability was evaluated on the Athelas One device by conducting a 48 hour stability study on nine different venous blood samples with low (0.5-3 K/µL, normal (4-10 K/µL), and high (>10 K/µL) WBC levels. The study was designed in accordance with recommendations from CLSI EP25-A.

Based on results evaluating deviation from pre-defined bias and precision criteria, the stability duration for all samples can be set to 24 hours with observed degradation at 48 hours for both the WBC and Neutrophil % parameters. Overall, all samples tested within 24 hours of collection time were found to meet the pre-set acceptance criteria of 7.5% CV for WBC precision, ± 7.5% Bias for WBC, 5% SD OR 15% CV for Neutrophils (updated based on Sysmex XW-100 Neut% CV criteria), and ± 10% Bias across the whole study.

Test Strip Stability over time

A 16 week test strip stability study was conducted to assess the shelf life stability of the Athelas test strips. The strips were tested weekly over 16 weeks to justify a 15 week expiration. The study was designed in accordance with recommendations from CLSI EP25-A.

In particular, the study was conducted over 16 weeks, across two test strip lots, 4 analyzers, two replicates, and one lot of quality control materials. Each week, we performed two replicates per two lots of strips across 3 levels of control fluid.

From the study it can be observed that none of the analyzed test strips manifested statistically significant degradation/drift over the 105-day study ($p > 0.05$) as recommended by the CLSI EP25-A regression slope analysis. The stability duration for all samples can be set to 98 days with no observed degradation at 105 days, the last time point of the study.

Clinical

Method Comparison

Method comparison studies were performed to assess the performance of the Athelas One analyzer when compared to the predicate Sysmex XE-5000 analyzer on a total of 312 patient samples taken at 3 point of care sites in the US. All samples were run in the Automated Sampling Modes in singlet on the XE-5000.

Samples covered clinical medical decision levels, and included normal and abnormal samples. The full reportable measuring ranges of the Athelas One analyzer were tested in method comparison. **All evaluation criteria (slope, r, bias at medical decision levels, overall bias, bland altman analysis, intercept) were met, and even more specifically: manufacture-defined criteria for equivalence between two predicate Sysmex XE-5000 devices was also met by the Athelas One.**

The overall results across three sites are shown in the table below.

Method Comparison Combined Site WBC and Neutrophil Results

Parameter	Interval	N	(r)	Slope			Intercept			Mean Bias	Mean % Bias
				Estimate	LCI (2.5%)	UCI (97.5%)	Estimate	LCI (2.5%)	UCI (97.5%)		
WBC	1.1 - 23 (K/µL)	312	0.99	0.978	0.958	1.000	-0.042	-0.159	0.086	-0.151	-2.31%
Neutrophil %	8 - 92.89 (%)	312	0.96	0.980	0.953	1.003	1.855	-0.530	3.677	0.636	1.18%

Flagging Comparison

As per Agency recommendation, a Flagging Comparison study was conducted to determine the ability for the Athelas One to successfully flag abnormal samples for manual review. The study design of a Sysmex XN series analyzer (FDA 510k K112605) was used, and a similar evaluation criteria of 90% flagging accuracy.

Morphological Flags

The results of the Athelas One morphological flagging compared to the XE-5000 flagging evaluation were divided into two categories: (1) No Flags, Negative Judgement (2) Patients with positive Morphology/Differential abnormalities - Flags present, Positive Judgement. The study was limited to WBC and DIFF related flags. The results obtained from the flagging comparison study met the specification of ≥ 90%.

		Sysmex XE - 5000		
		Positive (Abnormal)	Negative (Normal)	Total
Athelas One	Positive (Abnormal)	90	7	97
	Negative (Normal)	9	206	215
	Total	99	213	**312**

% Positive Agreement (Sensitivity) = 100 * 90/(90 + 9) = 90.91%
% Negative Agreement (Specificity) = 100 * 206/(206 + 7) = 96.71%
% Overall Agreement = 100 * (90 + 206) / (90 + 206 + 9 + 7) = 94.87%

Evaluation criteria for morphological flagging accuracy was met, and a similar analysis was conducted for distributional flagging as well. The flagging study covered a variety of abnormal samples that are flagged by the predicate, with a breakdown as follows:

Predicate Flag	Count
PLT Clumps?	15
Abn Lympho/L_Blasts?	51
Blasts?	46
Immature Gran?	29
Left Shift?	14

Matrix Comparison

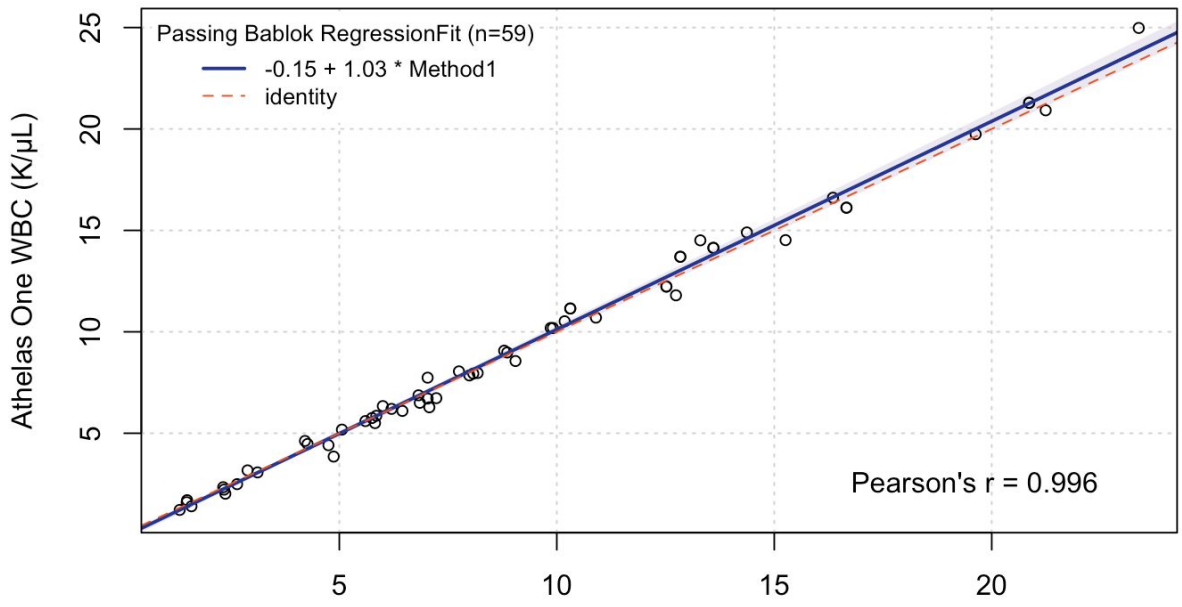
Experiments were conducted to determine the comparability of venous and capillary whole blood on the Athelas One device across 59 patients. These were in addition to the method comparison trials that used a combination of venous and capillary blood tested against venous samples run on the predicate device.

Capillary finger-prick blood samples were placed directly onto Athelas test strips from subjects. Venous whole blood samples were collected in K2EDTA vacutainer tubes for the same patients. The capillary whole blood and the venous whole blood samples were analyzed on Athelas One devices. It was concluded that there is no statistical difference between the systems when analyzing venous and capillary samples.

The regression parameters and 95% confidence interval of bias at the medical decision levels were calculated as per recommendation of CLSI EP5-A3 and H26-A2 and met all evaluation criteria. The information is summarized on the tables below:

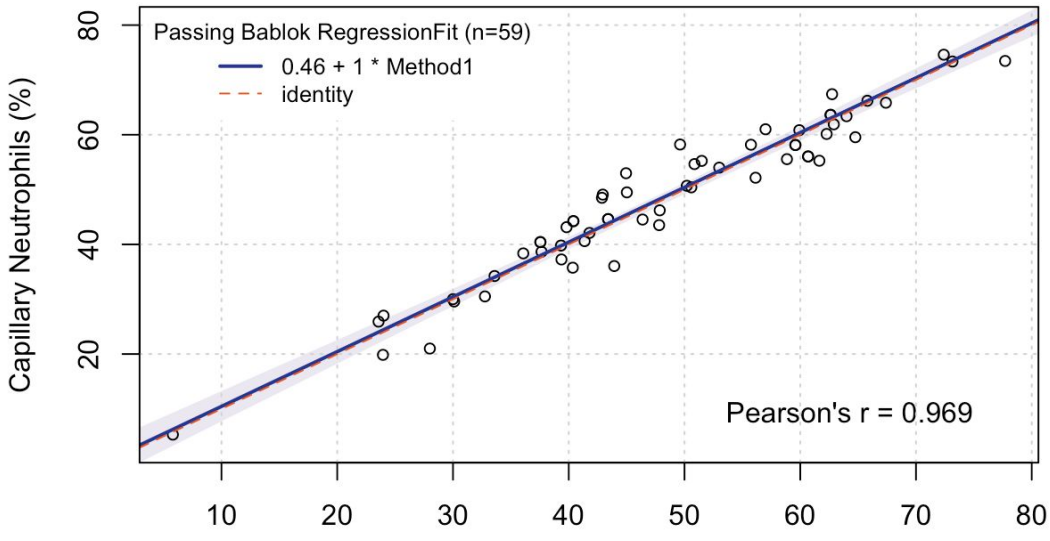
Parameter	Interval	N	(r)	Slope, 95% CI	Intercept	Mean Bias	Mean % Bias
WBC	1.33 - 23.38	59	0.996	1.026 (1.000, 1.055)	-0.145 (-0.319, 0.018)	0.056 (K/µL)	-0.588
Neutrophil %	5.8 - 74.6	59	0.969	0.999 (0.938, 1.058)	0.457 (-2.502, 3.614)	0.162 (Percentage Points)	-0.333

WBC Passing-Bablok Regression.



The 0.95-confidence bounds are calculated with the bootstrap(quantile) method.

Neutrophil % Passing-Bablok Regression.



The 0.95-confidence bounds are calculated with the bootstrap(quantile) method.

Conclusion

Through a range of CLSI recommended studies in clinical and bench settings, the Athelas One has been shown to be substantially equivalent to the Sysmex XE-5000 in generating WBC and Neut% parameters.