



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
INSTRUMENT ONLY**

**I Background Information:**

**A 510(k) Number**

K243348

**B Applicant**

Athelas Inc.

**C Proprietary and Established Names**

Athelas Home

**D Regulatory Information**

Product Code(s)	Classification	Regulation Section	Panel
GKZ	Class II	21 CFR 864.5220 - Automated Differential Cell Counter	HE - Hematology

**II Submission/Device Overview:**

**A Purpose for Submission:**

Clearance for modification of device to expand device use to point of care (POC) settings, addition of K2EDTA venous whole blood sample type, and modification of web-based software application

**B Measurand:**

White blood cell count (WBC) and percent neutrophil count (NEUT%)

**C Type of Test:**

Quantitative

### III Intended Use/Indications for Use:

#### A Intended Use(s):

See Indications for Use below.

#### B Indication(s) for Use:

The Athelas Home is indicated for the quantitative determination of white blood cells (WBC) and Neutrophil percentages (NEUT%) in capillary whole blood from fingerstick for patient self-testing with results viewable by healthcare professionals, and in capillary or K2EDTA venous whole blood for multiple-patient use in point-of-care settings. For self-testing, the Athelas Home is intended to be used by a single person and should not be shared. The Athelas Home is only to be used with Athelas Test Strips. The Athelas Home is intended for adult patients (aged 21 and older) at risk of neutropenia. For self-testing patients with psychiatric conditions, clinical judgment should be exercised when deciding the end-user and based on the instructions for use (IFU), the treating physician should determine which patients are competent to perform the test by themselves. Results obtained with the Athelas Home should not be the sole basis for patient diagnosis, treatment, or management of leukopenia and neutropenia, and all results should be evaluated by a healthcare provider. Prescription Use Only.

#### C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

### IV Device/System Characteristics:

#### A Device Description:

The Athelas Home is an automated cell counter system which consists of the Athelas Home analyzer and the Athelas Test Strips. Athelas Home returns quantitative WBC and NEUT% metrics. For self-testing, capillary whole blood samples are collected directly from finger. For point of care, capillary samples can be collected directly from finger or in K3EDTA tubes and for venous whole blood, samples are collected using K2EDTA. The Athelas Home also has Remote Lockout capabilities, such that a healthcare provider or manufacturer can remotely lock-out a device for safety in usage.

The Athelas Home uses image processing and microfluidics to measure WBC and NEUT% values from whole blood samples. A drop of blood is placed on the Athelas test strip either directly from the finger or via pipette from K3EDTA capillary or K2EDTA venous whole blood. The Athelas Home Test Strips are comprised of an upper optical panel, lower optical panel and a stain coated region containing methylene blue and cresyl violet stains. The images are automatically transmitted to the cloud server where they are processed and analyzed by an image processing algorithm. Access to results is role based on the web-based application where patients cannot access test results and results are viewable by healthcare professionals.

#### B Instrument Description Information:

##### 1. Instrument Name:

Athelas Home

2. Specimen Identification:

Specimen identification is manually entered at point of care.

3. Specimen Sampling and Handling:

Capillary whole blood is directly transferred via fingerstick to the Athelas test strip or using a K3EDTA micropipette which is inserted into the Athelas Home analyzer. Venous whole blood is collected in a K2EDTA tube and transferred by pipette to the Athelas test strip.

4. Calibration:

The device is factory calibrated. Automatic calibration is performed at the beginning of each test. No manual calibration is required by the end user.

5. Quality Control:

Auto-Check 3-Level Gridded Strip  
ATH-CHECK (3 level control)

**V Substantial Equivalence Information:**

**A Predicate Device Name(s):**

Athelas Home, Athelas One

**B Predicate 510(k) Number(s):**

K200828 , K181288

**C Comparison with Predicate(s):**

<b>Device &amp; Predicate Device(s):</b>	<u>K243348</u>	<u>K200828</u>	<u>K181288</u>
Device Trade Name	Athelas Home	Athelas Home	Athelas One
<b>General Device Characteristic Similarities</b>			
Parameters	WBC, NEUT%	Same	Same
Measurement Range	WBC: 1–25 x10 <sup>3</sup> /μL	Same	Same
Sample Volume	3.5 μL	Same	Same
Calibration	Factory calibrated and automatic calibration at the beginning of each test. No manual calibration by the end user.	Same	Same
Reagents	Cresyl Violet,	Same	Same

<b>Device &amp; Predicate Device(s):</b>	<u>K243348</u>	<u>K200828</u>	<u>K181288</u>
	Methylene Blue Stain (pre-loaded/coated dry and contained in test strip)		
Measuring 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.	Same	Same
Controls/ Calibrators	Auto-Check 3-Level Gridded Strip OR ATH-CHECK (3 level control)	Same	Same
<b>General Device Characteristic Differences</b>			
Intended Use/Indications For Use	The Athelas Home is indicated for the quantitative determination of white blood cells (WBC) and Neutrophil percentages (NEUT%) in capillary whole blood from fingerstick for patient self-testing with results viewable by healthcare professionals, and in capillary or K2EDTA venous whole blood for multiple-patient use	The Athelas Home is indicated for the quantitative determination of white blood cells (WBC) and Neutrophil percentages (NEUT%) in capillary whole blood. The Athelas Home system is for In Vitro Diagnostic use and for prescription use only. The Athelas Home is only to be used with Athelas Home Test Strips. The Athelas Home is indicated for 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

Device & Predicate Device(s):	<u>K243348</u>	<u>K200828</u>	<u>K181288</u>
	<p>in point-of-care settings. For self-testing, the Athelas Home is intended to be used by a single person and should not be shared. The Athelas Home is only to be used with Athelas Test Strips. The Athelas Home is intended for adult patients (aged 21 and older) at risk of neutropenia. For self-testing patients with psychiatric conditions, clinical judgment should be exercised when deciding the end-user and based on the instructions for use (IFU), the treating physician should determine which patients are competent to perform the test by themselves. Results obtained with the Athelas Home should not be the sole basis for patient diagnosis, treatment, or management of leukopenia and neutropenia, and all results should be evaluated by a healthcare provider. Prescription Use Only.</p>	<p>by patients and caregivers within home settings with results viewable by health care professionals. The Athelas Home is intended for patients at risk of neutropenia. For patients with psychiatric conditions, clinical judgement should be exercised when deciding the end-user, based on the instructions for use (IFU) of Athelas Home, the treating physician should determine which patients are competent to perform the test by themselves. The Athelas Home is indicated for adult populations only (aged 21 and older). Results obtained with the Athelas Home should not be the sole basis for patient diagnosis, treatment or management of leukopenia and neutropenia. All results should be evaluated by a healthcare provider. The Athelas Home is intended to be used by a single person and should</p>	<p>laboratories and for point of care settings. The Athelas One is only indicated for use in adult populations (aged 21 and older).</p>

Device & Predicate Device(s):	<u>K243348</u>	<u>K200828</u>	<u>K181288</u>
		not be shared. Prescription Use Only.	
Specimen Type	Capillary (Direct or K3EDTA) and K2EDTA Venous Whole Blood	Direct or K3EDTA Capillary Whole Blood	Direct Capillary and K2EDTA Venous Whole Blood
Setting	Home, Point-of-Care	Home	Point of Care, Clinical Laboratory
Target population	The Athelas Home is intended for patients at risk of neutropenia. For patients with psychiatric conditions, clinical judgment should be exercised when deciding the end-user. Based on the instructions for use (IFU) of Athelas Home, the treating physician should determine which patients are competent to perform the test by themselves. The Athelas Home is indicated for adult populations only (aged 21 and older).	Same	Adult populations (aged 21 and older).
Result Viewing	Results are remotely and securely transmitted to a web-based application with role-based access controls.	Results are remotely and securely transmitted via smartphone/tablet with the Athelas controlling mobile application to the prescribing physician or healthcare provider.	Results are shown on the mobile/tablet application used for system operation.

## VI Standards/Guidance Documents Referenced:

- IEC 60601-1 (2005)/(R) 2012: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Precision/Reproducibility:

Refer to K200828 and K181288

2. Linearity:

Refer to K200828 and K181288

3. Analytical Specificity/Interference:

Refer to K200828 and K181288

4. Accuracy (Instrument):

Refer to K200828 and K181288

5. Carry-Over:

Not applicable

### B Other Supportive Instrument Performance Characteristics Data:

1. **Cleaning and Disinfection Study:** The study evaluated cleaning and disinfection over 10,000 cycles, representing a two-year operational period with a total of 10,000 cycles. Three devices were tested using six fresh whole-blood venous samples with five replicates per sample with CaviWipes (EPA Reg. No. 46781-18) and results were compared against a comparator analyzer. Study met pre-defined acceptance criteria and demonstrated that there was no change in performance or external materials after 10,000 cleaning and disinfection cycles.

2. **Test strip Shelf-life stability:** A 26-month study was conducted to assess the shelf-life stability of the Athelas test strips. The strips were tested every 60 days across two test strip lots, four analyzers, three replicates, and multiple lots of quality control materials. Study met pre-defined acceptance criteria and stability of the Athelas test strips was established for 24 months.

## **VIII Proposed Labeling:**

The labeling supports the finding of substantial equivalence for this device.

## **IX Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.