



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

**I Background Information:**

**A 510(k) Number**

K221309

**B Applicant**

SigTuple Technologies Pvt. Ltd.

**C Proprietary and Established Names**

AI100 with Shonit

**D Regulatory Information**

Product Code(s)	Classification	Regulation Section	Panel
JOY	Class II	21 CFR 864.5260 - Automated Cell-Locating Device	HE - Hematology

**II Submission/Device Overview:**

**A Purpose for Submission:**

Clearance of new device

**B Type of Test:**

White blood cell (WBC) differential, red blood cell (RBC) and platelet morphology evaluation

**III Intended Use/Indications for Use:**

**A Intended Use(s):**

See Indications for Use below.

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

AI100 with Shonit is a cell locating device intended for in-vitro diagnostic use in clinical laboratories.

AI100 with Shonit is intended for differential count of White Blood Cells (WBC), characterization of Red Blood Cells (RBC) morphology and Platelet morphology. It automatically locates blood cells on peripheral blood smears and presents images of the blood cells for review.

A skilled operator, trained in the use of the device and in the review of blood cells, identifies and classifies each cell according to type.

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

Rx - For Prescription Use Only

## **IV Device/System Characteristics:**

### **A Device Description:**

The AI100 with Shonit device consists of a high-resolution microscope with LED illumination, and compute parts such as the motherboard, CPU, RAM, Wi-Fi dongle, solid state drive (SSD) containing AI100 with Shonit software, motorized XYZ stage, a camera with firmware, Programmable Circuit Board (PCB) and its firmware for driving motor and LED, Switched-mode power supply (SMPS), power supply and a casing. It is capable of handling one Peripheral Blood Smear (PBS) slide at a time. Romanowsky stains are used with the device.

The device moves the peripheral whole blood smear slide to the imaging area and performs pre-scan steps which involve identifying the optimal area of the smear for scanning. If the optimal area is not found, the slide is rejected, and the user is notified with appropriate error messages. If an optimal area is identified, scanning (capturing FOV images) proceeds from the center of the optimal area in an outward spiral fashion. Focusing is done at each image location to capture the most optimal image. The image at each field of view (FOV) is checked to ensure appropriate quality for image processing. The scan stops when the required number of FOVs are captured or required number of white blood cells (WBCs) are encountered, depending on the scan mode selected by the user. On each FOV image, image processing is applied to extract and classify WBCs, red blood cells (RBCs), and platelets.

WBCs are classified into Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Immature Granulocytes (IGs), Atypical Cells/Blasts and Nucleated Red Blood Cell (NRBCs). RBCs are classified according to size (Normocyte, Round Macrocyte, Ovalo Macrocyte, Microcyte) and shape (Normal, Target, Teardrop, Echinocyte, Elliptocyte, Ovalocyte, Fragmented). Platelets are classified into Normal, Large, Giant Platelets and Platelet Clumps. The device then allows the user to review the identified and classified cells, including cells that could not be classified and generate a microscopy report. Users may re-classify cells and add comments before approving the report.

## **B Instrument Description Information:**

1. Instrument Name:  
AI100 with Shonit
2. Specimen Identification:  
The slide's barcode is captured scanned and assigned to each case. The device also supports typing the barcode manually.
3. Specimen Sampling and Handling:  
A peripheral blood sample is collected in K2EDTA tubes. A thin blood film is wedged on a clean dry glass slide (a blood smear) and stained with Romanowsky stain. The slide is put on the stage for image capture.
4. Calibration:  
The device calibration should be performed by the SigTuple support team or by the end user/customer under the guidance of the SigTuple support team with Operational Qualification (OQ) slide every 6 months. Device calibration should be conducted:
  - Once every six months
  - After the device has been serviced
  - When a new OQ slide is provided
5. Quality Control:  
The AI100 with Shonit device performs self-test during startup after powering up or reset of the system. On startup, all software components and hardware components are checked and confirmed to behave normally before system is allowed to start a peripheral blood smear (PBS) scan. The quality is checked by performing the Operational Qualification (OQ) test and the Performance Qualification (PQ) test. Both tests use the OQ quality control slide. The OQ test should be conducted every three (3) months. In the OQ test, the parameters which determine functional and device performance metrics are tested automatically in a sequential order. The PQ test is for parameters which directly impact the image analysis and they are tested automatically in a sequential order. The PQ test should be conducted daily.

## **V Substantial Equivalence Information:**

- A Predicate Device Name(s):**  
CellaVision DC-1
- B Predicate 510(k) Number(s):**  
K200595
- C Comparison with Predicate(s):**

<b>Device &amp; Predicate Device(s):</b>	<u>K221309</u>	<u>K200595</u>
Device Trade Name	AI100 with Shonit	CellaVision DC-1
<b>General Device Characteristic Similarities</b>		
Intended Use/Indications For Use	<p>AI100 with Shonit is a cell locating device intended for in-vitro diagnostic use in clinical laboratories.</p> <p>AI100 with Shonit is intended for differential count of White Blood Cells (WBC), characterization of Red Blood Cells (RBC) morphology and Platelet morphology. It automatically locates blood cells on peripheral blood smears and presents images of the blood cells for review.</p> <p>A skilled operator, trained in the use of the device and in the review of blood cells, identifies and classifies each cell according to type.</p>	<p>CellaVision DC-1 is an automated cell-locating device intended for in-vitro diagnostic use in clinical laboratories.</p> <p>CellaVision DC-1 is intended to be used by operators trained in the use of the device.</p> <p>Peripheral Blood Application: The CellaVision Peripheral Blood Application is intended for differential count of white blood cells (WBC), characterization of red blood cell (RBC) morphology and platelet estimation.</p> <p>The CellaVision DC-1 with the Peripheral Blood Application automatically locates blood cells on peripheral blood (PB) smears. The application presents images of the blood cells for review. A skilled operator trained in recognition of blood cells, identifies and verifies the suggested classification of each cell according to type.</p>
Parameters	Automated cell-locating device for cell-location and identification of RBC, WBC or platelets for in-vitro use. Verification of results by human operator.	Same
Light Source	LED (Light Emitting Diode)	Same

Sample Source	Stained blood film on glass slides of peripheral whole blood.	Same
Sample Staining	Romanowsky stain	Same
Image interpretation requirements	A skilled operator is required to differentiate and finally modify and/or confirm the pre-classification/characterization of the located blood cells.	Same
Result format for WBC, RBC	The differential proportional count is normally based on 100 white blood cells. The number of WBCs can be modified if required. The result can be presented as a Count (count of located cells for the WBC cell type) or as % of total number of WBCs. The result of RBC characterization is presented as a grading for each morphology.	Same
User Interface	The User Interface is primarily designed to allow the user to view the images of the WBCs, RBCs and Platelets and review the classification. The user will be able to make corrections to the results and generate a report.	Same
Loading capacity	1 slide	Same
Immersion oil application	Manual Application	Same
Neural network	Neural network of convolutional type	Same
<b>General Device Characteristic Differences</b>	AI100 with Shonit	CellaVision DC-1
Analysis technique: WBC	White blood cells are located and counted by moving according to the outwardly increasing spiral path.	White blood cells are located/counted by moving according to the battlement track pattern

Analysis technique: Platelet	<p>Platelets are pre-classified based on morphology and images are displayed to the user. The operator verifies the suggested classification and confirms the qualitative output of 'Detected' vs 'Not Detected' for each platelet type.</p> <p>The user is presented with platelet images, classified based on morphology. The user can review the classification and confirm the qualitative output of Detected vs Not Detected against each platelet morphology category.</p>	<p>The operator manually counts and estimates the platelet concentration from the overview image according to a standardized procedure. From an overview image corresponding to eight high power fields the platelet level is estimated. The concentration of platelets is estimated by the user.</p>
Image Magnification	<p>The device has one objective lens at 40X magnification.</p>	<p>The device has two objective lenses, one at 10X and one at 100X magnification.</p>
Information transfer from instrument to Printer or network	<p>The current system does not interact with a laboratory information system (LIS)</p>	<p>The system can interact with a laboratory information system (LIS) The system will retrieve order data from the LIS and send results back to the LIS.</p>

## VI Standards/Guidance Documents Referenced:

- EVS-EN ISO 14971: 2019 Medical devices - Application of risk management to medical devices, (Recognition Number: 5-125)
- ISO 15223-1, Fourth Edition 2021-07 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements
- IEC 61010-1, Edition 3.1: 2017-01 - Standard for Safety for Electrical Equipment for Measurement, Control and Laboratory Use; Part 1: General Requirements
- IEC 62304, Edition 1.1: 2015-06 - Medical device software - Software life cycle processes
- IEC 62366-1, Edition 1.1 :2020-06 - Medical devices - Part 1: Application of usability engineering to medical devices
- CLSI EP05-A3 - Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition

- CLSI EP12-A2 - User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition
- CLSI H20-A2 - Reference Leukocyte (WBC) Differential Count (Proportional) an Evaluation of Instrumental Methods; Approved Standard - Second Edition
- ISTA 3B: 2013 - Packaged-Products for Less-Than-Truckload (LTL) Shipment
- IEC 61326-1 Edition 3.0 2020-10 - Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
- IEC 61326-2-6 Edition 3.0 2020-10 - Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

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

### A Analytical Performance:

#### 1. Precision:

- a) Repeatability was conducted at one site using 12 blood samples. The slides were either prepared manually or using an automated smearer and stained with Romanowsky stain. The repeatability study was conducted over 20 days x 2 runs per day x 2 replicates per run. The WBC repeatability results with the highest recorded standard deviations are provided. The Mean and Standard Deviation with the maximum 95% CI are provided for each cell type. The RBC and Platelet repeatability results are provided as the mean overall agreement for each subgroup. All results met the pre-defined acceptance criteria.

Cell Type	Repeatability		Between Run		Between Day		Within Lab	
	Mean (%)	SD (95%CI)	Mean (%)	SD (95%CI)	Mean (%)	SD (95%CI)	Mean (%)	SD (95%CI)
Neutrophil	65.4	2.605 (2.139, 3.333)	32.4	1.176 (0.994, 1.442)	65.4	2.487 (2.084, 3.086)	65.4	3.67 (3.049, 4.612)
Lymphocyte	24.4	3.212 (2.637, 4.109)	60.2	1.419 (1.198, 1.742)	60.2	1.42 (1.173, 1.798)	24.4	3.324 (2.871, 3.947)
Eosinophil	17.5	1.408 (1.156, 1.801)	2.1	0.352 (0.298, 0.429)	5.2	0.838 (0.711, 1.021)	17.5	1.496 (1.293, 1.777)
Monocyte	3.8	1.156 (0.949, 1.479)	3.8	0.832 (0.704, 1.019)	3.1	0.653 (0.541, 0.825)	3.8	1.507 (1.287, 1.818)
Basophil	0.5	0.417 (0.342, 0.533)	0.4	0.121 (0.102, 0.148)	0.5	0.232 (0.195, 0.286)	0.5	0.477 (0.408, 0.574)
Immature Granulocyte	9.7	1.608 (1.320, 2.058)	3	0.625 (0.530, 0.763)	9.7	0.801 (0.679, 0.975)	9.7	1.796 (1.542, 2.153)
Atypical Cell/Blast	49.9	2.614 (2.146, 3.345)	2.7	0.58 (0.486, 0.719)	49.9	1.448 (1.223, 1.777)	49.9	2.989 (2.557, 3.598)
NRBC	1.3	0.533 (0.438, 0.682)	1.3	0.199 (0.168, 0.245)	1.3	0.361 (0.302, 0.451)	1.3	0.674 (0.571, 0.822)

### Mean Agreement for RBC Size

RBC Size	Overall Agreement Mean Values
Round Normocytes	100%
Round Macrocytes	92%
Oval Macrocytes	93%
Anisocytosis	95%
Microcytosis	99%
Macrocytosis	95%

### Mean Agreement for RBC Shape

RBC Shape	Overall Agreement Mean Values
Normal	100%
Elliptocyte	99%
Teardrop	94%
Acanthocyte	96%
Target	91%
Fragmented	92%
Ovalocyte	99%
Poikilocytosis	99%

### Mean Agreement for Platelets

	Overall Agreement Mean Value
Platelet	100%
Giant Platelet	96%
Platelet Clump	83%

- b) Reproducibility was conducted using 13 blood samples. The study was conducted over five (5) days x five (5) runs x three (3) devices. Each slide was scanned 5 times per day per device. Each scan was considered one replicate. The WBC reproducibility results with the highest standard deviations are provided. The Mean and Standard Deviation with the maximum 95% CI is provided for each cell type. All results met the pre-defined acceptance criteria.

Cell Type	Repeatability		Between Day		Between Site		Reproducibility	
	Mean (%)	SD (95%CI)	Mean n (%)	SD (95%CI)	Mean (%)	SD (95%CI)	Mean (%)	SD (95%CI)
Neutrophil	25.6	2.158 (1.832, 2.627)	67.2	1.777 (1.002, 6.773)	62.1	2.024 (1.634, 2.659)	62.1	2.318 (1.330, 8.102)
Lymphocyte	46.5	2.806 (2.382, 3.417)	46.5	2.986 (1.644, 13.029)	46.5	2.606 (2.073, 3.510)	46.5	4.856 (3.485, 7.999)
Eosinophil	10.8	1.501 (1.274, 1.828)	10.8	2.095 (1.667, 2.822)	9.9	1.147 (0.969, 1.406)	10.8	2.578 (2.026, 3.545)
Monocyte	9.4	1.033 (0.877, 1.258)	5.9	1.094 (0.674, 2.814)	9.4	0.844 (0.715, 1.032)	9.4	1.424 (1.019, 2.362)
Basophil	0.2	0.292 (0.248, 0.356)	0.1	0.13 (0.070, 0.647)	0.2	0.205 (0.171, 0.255)	0.2	0.275 (0.175, 0.628)
Immature Granulocyte	5.3	1.231 (1.044, 1.498)	2.6	0.703 (0.394, 2.763)	6.1	1.03 (0.820, 1.383)	6.1	1.219 (0.714, 3.874)
Atypical Cell/Blast	31.8	2.096 (1.779, 2.552)	31.8	1.754 (0.937, 9.201)	31.8	3.222 (2.627, 4.169)	31.8	4.225 (2.639, 10.333)
NRBC	13	1.044 (0.886, 1.271)	13	1.466 (0.878, 4.214)	2	1.038 (0.878, 1.269)	2	1.27 (0.766, 3.541)

### Mean Agreement for RBC Size

RBC Size	Overall Agreement Mean Value
Round Normocytes	100%
Round Macrocytes	97%
Oval Macrocytes	89%
Anisocytosis	99%
Microcytosis	100%
Macrocytosis	96%

### Mean Agreement for RBC Shape

RBC Shape	Overall Agreement Mean Values
Normal	97%
Elliptocyte	96%
Teardrop	96%
Acanthocyte	91%
Target	97%
Fragmented	91%
Ovalocyte	99%
Poikilocytosis	95%

**Mean Agreement for platelet:**

	Overall Agreement Mean Values
Platelet	100%
Giant Platelet	92%
Platelet Clumps	93%

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Not applicable.

4. Accuracy (Instrument):

A method comparison study was conducted at four (4) sites comparing the AI100 with Shonit to manual microscopy. A total of 882 samples were collected encompassing healthy subjects and patients with specific disease conditions. Blood samples (K<sub>2</sub>EDTA) were collected, and one peripheral blood smear (PBS) slide was prepared for each sample (Romanowsky stain). The slides were randomly selected, blinded and evaluated by two examiners at each site. Passing-Bablok Regression analysis was performed for WBC differential and overall agreement, sensitivity and specificity were measured for WBC Distributional and Morphological abnormalities. Overall agreement, sensitivity and specificity were evaluated for RBC and PLT morphology. Calculations of 95% confidence intervals are also provided. The study met the pre-defined acceptance criteria.

**Regression results for WBC cell types**

WBC cell type	Parameter	Result (n = 882) with 95% CI
Neutrophil %	Slope	1.024 (1.016, 1.032)
	Intercept	-1.78 (-2.249, -1.346)
	Pearson's Correlation Coefficient	0.962
Lymphocyte %	Slope	1.025 (1.016, 1.034)
	Intercept	-0.587 (-0.881, -0.306)
	Pearson's Correlation Coefficient	0.96
Eosinophil %	Slope	1.029 (1.012, 1.05)
	Intercept	-0.039 (-0.07, -0.01)
	Pearson's Correlation Coefficient	0.907
Monocyte %	Slope	1.083 (1.051, 1.117)
	Intercept	-0.462 (-0.66, -0.304)
	Pearson's Correlation Coefficient	0.789

### Distributional and Morphological abnormalities for WBCs

WBC abnormality	Parameter	Results (n = 882) with 95% CI
Morphological abnormality	Overall Agreement	91.7% (90.4%, 92.8%)
	Sensitivity	95.3% (92.8%, 96.7%)
	Specificity	90.9% (89.4%, 92.2%)
Distributional abnormality	Overall Agreement	96.4% (95.5%, 97.2%)
	Sensitivity	91.0% (86.8%, 93.9%)
	Specificity	97.2% (96.3%, 97.9%)
Overall abnormality	Overall Agreement	95.0% (94.0%, 95.9%)
	Sensitivity	92.7% (89.2%, 95.0%)
	Specificity	95.4% (94.35%, 96.25%)

### RBC Morphology

RBC subgroup	Parameter	Results (n = 882) with 95% CI
Anisocytosis	Overall agreement	94.7% (93.6%, 95.7%)
	Sensitivity	91.1% (88.1%, 93.4%)
	Specificity	95.9% (94.7, 96.9%)
Poikilocytosis	Overall agreement	92.1% (90.7, 93.2%)
	Sensitivity	96.3% (94.8%, 97.3%)
	Specificity	88.1% (85.8%, 90.0%)
Macrocytosis	Overall agreement	95.5% (94.5%, 96.4%)
	Sensitivity	90.7% (87.0, 93.5%)
	Specificity	96.6% (95.5%, 97.4%)

### Platelet Morphology

PLT Cell type	Parameter	Results (n = 882) with 95% CI
Normal platelets	Overall agreement	100% (99.8%, 100%)
	Sensitivity	100% (99.8%, 100%)
	Specificity	100% (34.2%, 100%)
Giant platelets	Overall agreement	96.4% (95.4%, 97.1%)
	Sensitivity	99.1% (98.4%, 99.5%)
	Specificity	92.4% (90.3%, 94.1%)
Platelet clumps	Overall agreement	94.2% (93.0%, 95.2%)
	Sensitivity	91.6% (89.5%, 93.4%)
	Specificity	96.3% (94.9%, 97.3%)
Overall platelets	Overall agreement	96.8% (96.0%, 97.4%)
	Sensitivity	97.9% (97.1%, 98.4%)
	Specificity	94.6% (92.8%, 95.9%)

5. Carry-Over:

Not applicable.

### B Other Supportive Instrument Performance Characteristics Data:

1. Scan Mode Equivalence:

The scan mode equivalency study was conducted at one site with 200 samples collected and slides prepared using Romanowsky stain. The slides were scanned in each mode (i.e.,

100WBC, 200WBC, and 120 FOVs). There were 90 healthy individuals and 100 abnormal samples included in the study. Regression analysis with slope, intercept and 95% CI are calculated for the WBC differential. Overall agreement, positive percent agreement (PPA), Negative percent agreement (NPA) with 95% CI are evaluated for WBC Distributional and Morphological abnormalities, RBC morphology, and PLT morphology. The study met the pre-defined acceptance criteria.

#### **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.