September 19, 2023

SigTuple Technologies Pvt. Ltd.
% Jinjie Hu
President and Principal Consultant
Axteria BioMed Consulting Inc.
8040 Cobble Creek Circle
Potomac, Maryland 20854

Re: K221309
Trade/Device Name: AI100 with Shonit
Regulation Number: 21 CFR 864.5260
Regulation Name: Automated Cell-Locating Device
Regulatory Class: Class II
Product Code: JOY
Dated: February 22, 2023
Received: February 22, 2023

Dear Jinjie Hu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Min Wu -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221309

Device Name
AI100 with Shonit

Indications for Use *(Describe)*

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5 510(k) Summary

5.1 General Information

Submitter: SigTuple Technologies Pvt. Ltd.
First Floor, L-162, 14th Cross Road, Sector 6, HSR Layout,
Bangalore, Karnataka -56102
India

Contact Person: Jinjie Hu, PhD
Axteria BioMed Consulting Inc.
8040 Cobble Creek Circle
Potomac, MD 20854, USA
Tel: +1 (301) 814 4985
Email: jinjie.hu@axteriabiomed.com

Contact Person: Tathagato Rai Dastidar
SigTuple Technologies Pvt. Ltd.
First Floor, L-162, 14th Cross Road, Sector 6, HSR Layout,
Bangalore, Karnataka -56102, India
trd@sigtuple.com
+91-9341232063

Date Prepared: May 1, 2022

Purpose of Submission: To obtain a substantial equivalence for the AI100 with Shonit™

5.2 Measurand

White Blood Cells (WBC), Red Blood Cells (RBC) and Platelets (PLT).

5.3 Device Information

Proprietary Name of the Device:	AI100 with Shonit™
Common Name:	Automated cell locating device
Classification Name:	Automated cell-locating device
Regulation Number:	21 CFR 864.5260
Classification Name and Reference:	Class II
Device product Code:	JOY
Panel:	Hematology

5.4 Intended use/Indication 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 its characterizations.

5.5 Device Description

The AI100 with Shonit™ is for prescription use only.

5.5.1 Physical Properties of the AI100 with Shonit™

Weight: 40kg
Width: 553mm
Depth: 485mm
Height: 485mm

5.5.2 Components of the AI100 with Shonit™

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, SSD containing AI100 with Shonit™ software, motorized XYZ stage, a camera with firmware, PCB and its firmware for driving motor and LED, SMPS, power supply and a casing. It is capable of handling one Peripheral Blood Smear (PBS) slide at a time.

Software plays an intrinsic role in the AI100 with Shonit™ device, and the combination of hardware and software works together for the device to achieve its intended use. The main functions of the software can be summarized as follows:

- Allow the user to set up the device and perform imaging of a PBS slide.
- Control the hardware components (Camera, LEDs, Stages, etc) to take images of a PBS slide.
- Store and manage images and other data corresponding to the PBS slide and present them to the user.
- Analyze images and allows user to identify components in the images and create a report for review.
- Allow the user to finalize, download and print a report.

5.5.3 Consumables required to produce blood smears to be used on AI100 with Shonit™

The following consumables are needed to produce blood smears:

- Romanowsky stain such as Leishman, Wright Giemsa (WG) or Wright (W) stains
- Slides
- EDTA sample tube (K_2EDTA)
- Automatic slide maker-stainer, or smear/stain slides manually

5.5.4 Specimen Identification

Peripheral blood samples typically flagged by a cell-counter indicating an abnormal morphology.

5.5.5 Anticoagulant

K_2EDTA is the anticoagulant to be used. All samples used in the analytical and clinical studies were collected using K_2EDTA as the anticoagulant.

5.5.6 Calibration

Device calibration is required to ensure that the system performs optimally. The device calibration is to be performed under the following circumstances -

1. Once every six months.
2. After the device is serviced by a SigTuple technician.
3. If and when a new OQ slide is issued by SigTuple.

5.5.7 Mini-Calibration

Mini-calibration is required to ensure that the system performs optimally. The mini-calibration is to be performed under the following circumstances –

1. When the device is serviced (and recommended by the SigTuple support team).

5.5.8 Quality Control

The AI100 with Shonit™ device performs a series of self-tests during startup after powering up or a reset of the system. On startup, all software components and hardware components are checked and confirmed to be behaving normally before the system is allowed to start a PBS scan. Communication with the hardware is tested continuously during system operation and appropriate messages are displayed to the user if any errors occur during its operation.

5.5.8.1 Performance Qualification

The AI100 with Shonit™ device contains a set of tests to check and verify whether all its components are behaving as expected and performing within their normal operating ranges. It uses an Operational Qualification (OQ) slide that is provided to the user along with the device. The tests are mostly automated and only require the user to trigger the tests; the exceptions are the test that checks the LCD touchscreen as well as the loading and unloading of the OQ slide. This set of tests is recommended to be run daily by the user before using the system.

5.5.8.2 Operational Qualification

In addition to the Performance Qualification tests, another set of tests is also provided and these test more functionalities and components of the device in a more detailed manner. This set of tests is of longer duration and does not need to be performed daily; they are recommended to be run once every 3 months. These tests require the same OQ slide and need no user intervention other than inserting the OQ slide and touching the LCD touchscreen when prompted.

5.5.9 Principle of Operation

The principle of operation of the AI100 with Shonit™ device broadly mirrors the reference method of manual microscopy.

The first step is to find whether the PBS slide is well prepared and is suitable for microscopy reading and report preparation. Once the user enters information about the slide on the UI and triggers the scan, the device moves the 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 FOV is checked to ensure appropriate quality for image processing. The scan stops when the required number of FOVs are captured or the required number of 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, RBCs, and Platelets. This is a multi-step process for each cell type and the type of processing varies between each of them. WBCs are classified into Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Immature Granulocytes (IGs), Atypical Cells / Blasts and NRBCs. RBCs are classified according to size (Normocyte, Round Macrocyte, Ovalo Macrocyte) 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. The user may re-classify cells and add impressions as they deem fit and approve the report. The report is then available for printing and/or distribution according to the workflow of the laboratory/hospital.

5.6 Substantial Equivalence Information

5.6.1 Technological Characteristics Comparison with Predicate Device

Like the predicate device, AI100 with Shonit™ locates white blood cells, stores digital images of the cells and displays the images in an organized manner and suggests a cell class for each cell to aid operators in performing the differential count procedure. A competent operator is required to verify or modify the suggested classification of each cell. It is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells. Like the predicate device, AI100 with Shonit™ presents images from which it is possible to characterize red blood cells according to size and shape and identify platelet morphology.

5.7 Principle of Operation/Comparison with Predicate Device

The method requires a skilled operator to review the images of the cells as does the predicate device. See below for the substantial equivalence comparisons.

Table 1: Comparison with Predicate Device: Similarities

Characteristic	CellaVision® DC-1 (K200595)	AI100 with Shonit™ (K221309)
Intended Use	CellaVision® DC-1 is an automated cell-locating device intended for in-vitro diagnostic use in clinical laboratories. CellaVision® DC-1 is intended to be used by operators trained in the use of the device. 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. 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	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.

	the suggested classification of each cell according to type.	
Intended Use Population	The intended use population is patients whose blood samples have been flagged as abnormal by an automated cell counter.	Same
Analytes	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
Major Parts of the System (that are similar)	• Computer module (integrated) • Digital color camera • Control unit (integrated in camera) • Casing • Data base	Same
Light Source	LED (Light Emitting Diode)	Same
Sample Source	Stained blood film on glass slides of peripheral whole blood.	Same
Sample Preparation	Romanowsky stain	Same
Analysis Technique WBCs	White blood cells are pre-classified and presented to the operator. To complete the differential, the operator needs to verify that all located WBCs are correctly classified. All cells must be classified and verified before the order can be signed.	Same
Analysis Technique RBCs	The device pre-characterizes the RBC morphology based on the overview image of the RBC monolayer, followed by the operator's verification or modification of the suggested results.	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 the	Same

	number of located cells or as % of total number of WBCs. The result of RBC characterization is presented as a grading for each morphology.	
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
Operators' Competence	The operator is trained in the recognition of blood cells and in the use of the device.	Same
Decision Support	The device includes white blood cell reference cells.	Same
Loading Capacity	1 slide	Same
Immersion Oil Application	Manual application	Same
Neural Network	Neural network of convolutional type	Same

Table 2: Comparison with Predicate Device: Differences

Characteristic	**CellaVision® DC-1 (K200595)**	**AI100 with Shonit™ (K221309)**
Major Parts of the System (that are different)	• Motorized microscope • XY stage	• Non-motorized microscope • XYZ stage • Cloud reporting platform
Analysis Technique WBC	White Blood Cells: Cells are located/counted by moving according to the battlement track pattern.	White Blood Cells: Cells are located and counted by moving according to the outwardly increasing spiral path.
Analysis Technique Platelet	Platelets: 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.	Platelets: 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. The system uses a qualitative output to show results for platelets.

		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.
Image Magnification	The device has two objective lenses, one at 10X and one at 100X magnification.	The device has one objective lens at 40X magnification.
Information Transfer from Instrument to Printer or Network	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.	The current system does not interact with a laboratory information system (LIS).
Decision Support	The operator can add his/her own reference cells.	The operator cannot add his/her own reference cells.
Calibration	Recommended calibration once a year by a service engineer.	Recommended calibration once in 6 months by a service engineer or the user.
Anticoagulant	Clinical study was done using K_3 EDTA and scientific justification (unrelated to the device) was given to prove equivalence between K_2 EDTA and K_3 EDTA.	Clinical study was done using K_2 EDTA.

5.8 Brief Discussion of Clinical Tests Supporting a Determination of Substantial Equivalence

Studies with blood samples collected in K_2EDTA tubes have been performed to confirm equivalence with the standard method (microscopy review result of the blood smear) for differentiation of WBCs, characterization of RBCs and identify Platelet morphology with the subject device AI100 with Shonit™.

5.9 Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical Safety and EMC testing was conducted on the AI100 with Shonit™. The tests show that the AI100 with Shonit™ is in conformity with the following standards:

- IEC 61010-1: 2010 (Amendment 1:2016)
- IEC 61010-2-101: 2015
- IEC 60601-1-2:2014+A1:2020
- IEC 61326-1: 2012 (EN 61326-1:2013)
- IEC 61326-2-6: 2012 (EN 61326-2-6:2013)

We have performed an analysis and Gap Assessment with the newer version of each standard and concluded that AI100 with Shonit™ is in compliance with the following updated versions of the standards:

- IEC 61010-1: 2017

- IEC 61010-2-101: 2018
- IEC 61326-1: 2020-10
- IEC 61326-2-6: 2020-10

5.10 Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and Staff, "Guidance for the Content of premarket Submissions for Software Contained in Medical Devices." The software application was considered as a "moderate" level of concern, since a malfunction, failure, or latent design flaw in the software could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that could lead to a minor injury.

5.11 Analytical Performance: Precision, Repeatability

The repeatability study was conducted in a clinical setting using a single instrument at a single site. The study outline for the repeatability study known as 20 x 2 x 2 single-site repeatability study was based on CLSI EP05-A3 (Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition).

5.11.1 WBC Repeatability

12 samples were used for the study. All slides were processed on AI100 with Shonit™ according to the study outline of 20 x 2 x 2 single-site repeatability study. The evaluation was performed on the pre-classified results suggested by the device. The proportional cell count in percent for each cell class was used to estimate variance components for repeatability (repeatability standard deviation, between-run standard deviation, between-day standard deviation and within-laboratory standard deviation). All tests met acceptance criteria.

5.11.2 RBC Repeatability

12 samples were used for the study. All slides were processed on the AI100 with Shonit™ according to the study outline of 20 x 2 x 2 single-site repeatability study. The evaluation was performed on the pre-characterized results suggested by the device. Repeatability in terms of RBC shape and size for each morphological characteristic was evaluated. Overall agreement for the grades for RBC size (Normocytes, Oval macrocytes, Round macrocytes) and RBC Poikilocytes (Normal Cells, Echinocytes, Target cells, Elliptocytes, Teardrop cells, Fragmented cells, Ovalocytes) for each run were used for analysis. All tests met acceptance criteria.

5.11.3 PLT Repeatability

12 samples were used for the study. All slides were processed on the AI100 with Shonit™ according to the study outline of 20 x 2 x 2 single-site repeatability. The evaluation was performed on the pre-characterized results suggested by the device. Overall agreement for the qualitative grade – 'Detected/Not Detected' for each run was used for analysis. All tests met acceptance criteria.

5.12 Analytical Performance: Reproducibility

The reproducibility study was performed according to the CLSI's EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition.

A 3x5x5 reproducibility study for the analyses of white blood cells differential, RBC and platelet classification was performed across three different devices. The study was conducted using 13 test samples, for 5 testing days, using 5 replicates scanned on the three devices.

In total, 975 scans were analyzed. For each tested sample, Standard Deviations were estimated for the variance components: between day, within-device, between device, and reproducibility.

5.12.1 WBC Reproducibility

13 samples were included in the study. One slide was prepared from each sample and processed on three instruments for five days (a 3 x 5 x 5 study). The evaluation was performed on the pre-classified results suggested by the device. The proportional cell count in percent for each cell class was used to estimate variance components for reproducibility (reproducibility standard deviation, repeatability standard deviation, between-day standard deviation, within-laboratory standard deviation and between-site standard deviation). All tests met acceptance criteria.

5.12.2 RBC Reproducibility

13 samples were included in the study. One slide was prepared from each sample and processed on three instruments for five days (a 3 x 5 x 5 study). The evaluation was performed on the pre-characterized results suggested by the device. Reproducibility in terms of RBC shape and size for each morphological characteristic was evaluated. Overall agreement for the grades for RBC size (Normocytes, Oval macrocytes, Round macrocytes) and RBC Poikilocytes (Normal Cells, Echinocytes, Target cells, Elliptocytes, Teardrop cells, Fragmented cells, Ovalocytes) for each run were used for analysis. All tests met acceptance criteria.

5.12.3 PLT Reproducibility

13 samples were included in the study. One slide was prepared from each sample and processed on three instruments for five days (a 3 x 5 x 5 study). The evaluation was performed on the pre-characterized results suggested by the device. Overall agreement for qualitative grade – 'Detected'/'Not Detected' output for each run was used for analysis. All tests met acceptance criteria.

5.12.4 Linearity

Not applicable

5.12.5 Carryover

Not applicable

5.12.6 Interfering Substance

Not applicable

5.13 Method Comparison Study

A method comparison study was conducted to compare the results achieved by trained qualified reviewers using the AI100 with Shonit^{TM} system to the results achieved by performing manual microscopy. The study was performed according to the CLSI H20-A2: Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard – Second edition guidelines.

A total of 882 samples were collected and analyzed across four sites. Out of these 882 samples, 298 samples were normal and 584 samples were abnormal. The sample distribution followed the CLSI H20-A2 standard. The study included samples across all age groups – newborn, infant, child, adolescent and adults. Blood samples were collected in K_2 EDTA vacutainers for the study and peripheral blood smears were prepared and stained using

Romanowsky stain. The stained slides were read by two medical reviewers at each site both on the AI100 with Shonit™ device and manual microscope (reference method).

White Blood Cells (WBCs)

The below table summarizes the results of Passing-Bablok regression comparison method for the multi-site study.

Table 3: Regression Analysis for WBC - AI100 with Shonit™ vs Manual Microscopy

WBC Cell type	Slope 95% CI	Intercept 95% CI	Pearson's correlation coefficient (r)
Neutrophils (%)	1.024 (1.016, 1.032)	-1.78 (-2.249, -1.346)	0.962
Lymphocytes (%)	1.025 (1.016, 1.034)	-0.587 (-0.881, -0.306)	0.960
Eosinophils (%)	1.029 (1.012, 1.05)	-0.039 (-0.07, -0.01)	0.907
Monocytes (%)	1.083 (1.051, 1.117)	-0.462 (-0.66, -0.304)	0.789

All the 95% CI values for slope and intercept met the acceptance criteria for the accuracy measured by Passing-Bablok regression for WBC differential counts.

Sensitivity, specificity, and overall agreement for distributional WBC abnormalities (Neutrophils, Lymphocytes, Monocytes, and Eosinophils), morphological WBC abnormalities (Immature Granulocytes, Atypical Cells/Blasts, and NRBCs) and overall WBC abnormalities were evaluated between the candidate device and manual microscopy. The results are summarized in the table below.

Table 4: Distributional and Morphological Abnormalities for WBCs – AI100 with Shonit™ vs Manual Microscopy

WBC Abnormality	Morphological Abnormality 95% CI	Distributional Abnormality 95% CI	Overall 95% CI
Overall Agreement	91.7% (90.4%, 92.8%)	96.4% (95.5%, 97.2%)	95.0% (94.0%, 95.9%)
Sensitivity	95.3% (92.8%, 96.7%)	91.0% (86.8%, 93.9%)	92.7% (89.2%, 95.0%)
Specificity	90.9% (89.4%, 92.2%)	97.2% (96.3%, 97.9%)	95.4% (94.3%, 96.3%)

All the 95% CI values for sensitivity, specificity, and overall agreement for distributional WBC abnormalities, morphological WBC abnormalities and overall WBC abnormalities met the acceptance criteria.

Red Blood Cells (RBCs)

Sensitivity, specificity, and overall agreement for RBC morphologies (size and shape) were evaluated between the candidate device and manual microscopy. The results are summarized in the table below.

Table 5: Overall Agreement for RBC Size and Shape between AI100 with Shonit™ vs Manual Microscopy

RBC Abnormality	Sensitivity 95% CI	Specificity 95% CI	Overall Agreement 95% CI
Anisocytosis	91.1% (88.1%, 93.4%)	95.9% (94.7%, 96.9%)	94.7% (93.6%, 95.7%)
Macrocytosis	90.7% (87.0%, 93.5%)	96.6% (95.5%, 97.4%)	95.5% (94.5%, 96.4%)
Poikilocytosis	96.3% (94.8%, 97.3%)	88.1% (85.8%, 90.0%)	92.1% (90.7%, 93.2%)

All the 95% CI values for sensitivity, specificity, and overall agreement for RBC morphologies (size and shape) met the acceptance criteria.

Platelets

Sensitivity, specificity, and overall agreement for platelet morphologies were evaluated between the candidate device and manual microscopy. The results are summarized in the table below.

Table 6: Overall Agreement for Platelet – Comparison between AI100 with Shonit™ vs Manual Microscopy

Platelet Type	Sensitivity 95% CI	Specificity 95% CI	Overall Agreement 95%CI
Platelets	100% (99.8%, 100%)	100% (34.2%, 100%)	100% (99.8%, 100%)
Giant Platelets	99.1% (98.4%, 99.5%)	92.4% (90.3%, 94.1%)	96.4% (95.4%, 97.1%)
Platelet clumps	91.6% (89.5%, 93.4%)	96.3% (94.9%, 97.3%)	94.2% (93.0%, 95.2%)
Overall Platelets	97.9% (97.1%, 98.4%)	94.6% (92.8%, 95.9%)	96.8% (96.0%, 97.4%)

All the 95% CI values for sensitivity, specificity, and overall agreement for platelet morphologies met the acceptance criteria.

5.14 Proposed Labeling

The labeling satisfies the requirement of 21 CFR Part 809.subpart B.

5.15 Conclusion

AI100 with Shonit™ has the same intended use as the predicate device, the CellaVision® DC-1 analyzer cleared in K200595. AI100 with Shonit™ and the predicate device are quantitative, automated cell locating devices for In Vitro Diagnostic Use in clinical laboratories with the same Intended Use.

Both these cell locators can be used with K_2 EDTA whole blood. Both systems are to be used by trained medical professionals to identify WBCs, RBCs and Platelets. Both systems can handle only one peripheral blood smear slide at a time which is smeared and prepared using Romanowski stain. Both systems have LED light source, use microscopic lenses and a camera for imaging, and deploy neural networks of convolution type for image analysis.

The differences have been analyzed and found to be minor technological differences which do not affect the safety and effectiveness of the device.

The analytical and clinical performance studies of the AI100 with Shonit™ were conducted per the study protocols covering all cell types and morphologies that the system is intended to identify. For WBCs, samples covered both normal and abnormal levels for neutrophils, eosinophils, lymphocytes, and monocytes. Samples with abnormal concentrations of IGs, atypical cells or blasts and NRBCs were also included in the study. For RBCs, the samples studied covered all morphological characteristics. For Platelet morphology, samples with Platelet abnormalities such as Giant Platelets and Platelet Clumps, were covered.

The clinical and analytical performance comparison study results demonstrate that the AI100 with Shonit™ system is substantially equivalent to the predicate device (CellaVision® DC-1) system. The studies met their predefined acceptance criteria successfully. The device is safe to use with no adverse events reported during the study.