510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K220013

B Applicant

Scopio Labs Ltd.

C Proprietary and Established Names

X100HT with Slide Loader with Full Field Peripheral Blood Smear (PBS) Application

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:

The purpose of the submission is to add a Slide Loader to the cleared X100 with Full Field PBS (K201301) that allows up to 30 slides to be analyzed.

B Type of Test:

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

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The X100HT with Full Field Peripheral Blood Smear Application is intended to locate and display images of white cells, red cells, and platelets acquired from fixed and stained peripheral blood smears and assists a qualified technologist in conducting a WBC differential, RBC morphology evaluation, and platelet estimate using those images. For in vitro diagnostic use only. For professional use only.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

The X100HT with Slide Loader and Full Field Peripheral Blood Smear automatically locates and presents images of blood cells on peripheral blood film smears. The user browses through the imaged smear to gain high-level general impression. The user reviews the suggested classification of each white cell according to type and may manually change the suggested classification of any cell. The user can evaluate red cell morphology on observed images. The user reviews each detected platelet and the suggested platelet estimation and may manually change the detections or the estimation. The X100HT with Full Field PBS is intended to be used by skilled users, trained in the use of the device and in the identification of blood cells.

The X100HT with Full Field PBS shares the same intended use as the previously 510(k)-cleared X100 Full Field PBS (K201301). Specifically, it is comprised of the identical X100 scanner and Full Field PBS application, but it is assembled with an external Slide Loader, and additional slide locks were added to the X100 tray. A minor software change to the 'Scanning' interface was also introduced to allow interaction with the Slide Loader. The Slide Loader was designed as an optional manufacturer assembly part to the cleared X100 scanner, to replace this preliminary need of a manual mounting media application and a coverslip placement. As with the predicate, the preparation of the stained blood smear and barcoding of the slide are identical for the X100HT and are still externally prepared by the user, either manually or by third party devices. The Slide Loader comes with three cassettes, each cassette may hold up to 10 slides. The user manually inserts non-cover slipped PBS-stained blood smear slides into the cassettes. In turn, the Slide Loader, upon the user's request, adds mounting media, cover slips each slide and loads them sequentially into the X100 for processing.

B Instrument Description Information:

1. Instrument Name:
   X100HT with Slide Loader with Full Field Peripheral Blood Smear Application

2. Specimen Identification:
   The slide's barcode is captured automatically and assigned to each case. The device also supports typing the barcode manually.

3. Specimen Sampling and Handling:
   A peripheral blood sample collected in K2EDTA or K3EDTA tubes is mixed manually or automatically. A thin blood film is wedged on a clean dry glass slide (a blood smear) and stained with Romanowsky stain. The user manually places up to 30 slides into 3 extractable

cassettes and inserts them into the Slide Loader. The Slide Loader sequentially inserts the slides into the scanner. The instrument automatically coverslips and adds immersion oil to slide for scanning.

4. Calibration:
   The Full Field PBS system requires initial calibration for its mechanical and optical performances. An initial calibration process is performed on a standard blood smear slide as part of the manufacturing process of the device. The calibration is verified after installation by a technician or a qualified operator. Calibration can also be performed if a problem arises in the daily QC testing.

5. Quality Control:
   Quality Control (QC) testing is performed on a daily basis ("daily QC"). The daily QC involves testing a standard blood smear slide prepared on the same day. During the daily QC the user reviews the images received from the Full Field PBS and verifies that at least 95% of the WBCs in the scanned image were identified and located correctly by the system. The Full Field PBS application maintains a digital QC log, enabling the user to review and to track the history of QC testing performed by the Full Field PBS.

V Substantial Equivalence Information:

A Predicate Device Name(s):
X100 with Full Field Peripheral Blood Smear (PBS) Application

B Predicate 510(k) Number(s):
K201301

C Comparison with Predicate(s):

Device & Predicate Device(s):	K220013	K201301
Device Trade Name	X100HT with Full Field PBS	X100 with Full Field PBS
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended to locate and display images of white cells, red cells, and platelets acquired from fixed and stained peripheral blood smears and assists a qualified technologist in conducting a WBC differential, RBC morphology evaluation, and platelet estimate using those images. For	Same

	in vitro diagnostic use only. For professional use only.	
Sample Type	Peripheral whole blood	Same
Sample Smear	Sample is smeared on a glass microscope slide (Either manually or by third party device).	Same
Sample Staining	Sample's smear is fixed and stained with Romanowsky stain. (Either manually or by third party device)	Same
Sample Identification	Sample's microscope slide is identified by a unique barcode label. (Barcode label is applied either manually or by third party device).	Same
High-Resolution Image Acquisition	Fully automated scan and image acquisition. Captures multiple images under plurality of illumination conditions and reconstructs a 100X magnification image of the viewed area, without the need for immersion oil.	Same
Analysis Technique: White Blood Cells	WBCs are located/counted by moving according to the battlement pattern (ensuring that each cell is counted only once). Cell images are analyzed using standard mathematical methods, including deterministic artificial neural networks (ANN's) trained to distinguish between classes of white blood cells. The cell images are pre-classified, and the user reviews the	Same

	suggested classification, and accepts or reclassifies the images.	
Analysis Technique: Red Blood Cells	Red blood cells: The device presents an overview image. The examiners characterize red blood cell morphology from the image.	Same
Daily QC	The QC procedure controls for slide preparation (both smearing and staining) and device performance. If the QC procedure does not pass, the operator must resolve the problem and rerun the QC before processing samples.	Same
Analysis Technique: Platelets	Platelets are automatically located/counted by moving according to the battlement pattern (ensuring that each cell is counted only once). The user reviews the suggested estimate of the platelet concentration, and accepts or modifies the result.	Same
Pre-classified WBC	Cell images are grouped into eighteen (18) categories: • Band Neutrophils • Segmented Neutrophils • Lymphocytes • Atypical Lymphocytes • Large Granular Lymphocytes • Aberrant Lymphocytes • Monocytes • Eosinophils • Basophils	Same

	• Promyelocyte • Metamyelocytes • Myelocytes • Blasts • Plasma Cells • Nucleated Red Blood Cells • Unclassified • Smudge cells • Dirt	
Power Source	120/100 – 240V, 1.5A, 50 – 60 Hz	Same
General Device Characteristic Differences		
Sample Cover Slipping	The X100HT automatically applies mounting media and a glass cover slip onto the sample's microscope slide.	User manually applies mounting media and a glass cover slip onto the sample's microscope slide.
Sample Loading	The user manually places up to 30 slides into 3 extractable cassettes, and inserts them into the Slide Loader. The Slide Loader sequentially inserts the slides into the X100 scanner.	User manually inserts up to 3 slides into an extractable tray, and manually inserts the tray in to the X100 scanner.
Dimensions	Width: 39cm Length: 42cm Height: 55cm	Width: 32cm Length: 32cm Height: 35cm
Weight	33kg	14kg

VI Standards/Guidance Documents Referenced:

- IEC 62471 First edition 2006-07: Photobiological safety of lamps and lamp systems, FDA recognition number 12-249. Test Report is documented in the company's QMS, and may be submitted for agency review by request.
- IEC 60601-1-2:2014, 4th edition: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests, FDA recognition number 19-8. Test Report is documented in the company's QMS, and may be submitted for agency review by request.

- ISO 14971:2019, Medical Devices - Application of risk management to medical devices, FDA recognition number 5-125.
- IEC 62304:2006+AMD1:2015 CSV, Medical Device Software – Software Life-Cycle Processes, FDA recognition number 13-79.
- ISO 13485:2016(en) Medical devices — Quality management systems — Requirements for regulatory purposes
- IEC 61010-2-101:2015 / EN 61010-2-101: 2017 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical 038
- equipment. Test Report is documented in the company's QMS, and may be submitted for agency review by request.
- IEC / EN 61010-1: 2010 (3rd Edition) Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements. Test Report is documented in the company's QMS, and may be submitted for agency review by request.
- FCC CFR 47 Part 15 Subpart B, ANSI C63.4:2014. Test Report is documented in the company's QMS, and may be submitted for agency review by request.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Refer to K201301

2. Linearity:

   Refer to K201301

3. Analytical Specificity/Interference:

   Refer to K201301

4. Accuracy (Instrument):

   Refer to K201301

5. Carry-Over:

   Not applicable

B Other Supportive Instrument Performance Characteristics Data:

Verification and Validation

1. Oil application:
   The Oil application study was performed to evaluate automatic application of mounting media (oil) onto the slide. The study was conducted using three (3) X100HT devices, each

device tested with 1,000 consecutive oil application procedures totaling 3,000 slides. The study results passed pre-defined acceptance criteria.

	X100HT-Test Device #1	X100HT-Test Device #2	X100HT-Test Device #3
Average oil coverage of the scan area	99.88%	99.71%	99.66%
Average bubble count	0.06%	0.19%	0.22%
Average bubble coverage	0.09%	0.28 %	0.36%

2. Cover Slip application:

   The Cover Slip application study was performed to evaluate automatic placement of glass coverslips onto the slide. The study was conducted using three (3) X100HT devices, each device tested with 1,000 consecutive coverslip application procedures totaling 3,000 slides. The study results passed pre-defined acceptance criteria.

	X100HT-Test Device #1	X100HT-Test Device #2	X100HT-Test Device #3
Successful cover slip placement, from 1000 slides per device	99.7% 997/1000	99.8% 998/1000	99.7% 997/1000

3. Loading of Slides:
   The study was performed to evaluate automatic loading of the slides. The study was conducted using three (3) X100HT devices, each device tested with 100 loading cycles and Full Field scanning. In total 300 were loaded and scanned. The study results passed pre-defined acceptance criteria.

	X100HT-Test Device #1	X100HT-Test Device #2	X100HT-Test Device #3
Number of scans with % FOVs in focus.	100/100 (100%)	100/100 (100%)	100/100 (100%)

4. Complete process from Oil application to Loading slides:
   The study was performed to evaluate a complete cycle of oil application, glass cover slipping, and automatic loading of the slides. The study was conducted using three (3) X100HT devices, each device tested with 1000 cycles totaling 3000 complete cycles. The study results passed pre-defined acceptance criteria.

	X100HT-Test Device #1	X100HT-Test Device #2	X100HT-Test Device #3
Number of successful operational cycles	995/1000 (99.5%)	992/1000 (99.2%)	993/1000 (99.3%)
Number of aborted cycles due to system alerts, which required user intervention	5/1000 (0.5%)	8/1000 (0.9%)	7/1000 (0.8%)

5. Electrical Safety

   To evaluate electrical safety, testing was performed for electromagnetic (EMC) and Electrical Safety according to consensus standards. The study met pre-defined acceptance criteria.

6. Scanning Module
   The Scanning page module was changed to support the 'start scan' option for a cassette rather than a slide. The change was tested throughout the different verification and validation tests for any user interface errors. The study results passed pre-defined acceptance criteria.

7. Automatic Workflow
   The Automatic workflow study was performed with 30 clinical peripheral blood smear (PBS) Romanowsky-stained test slides prepared and collected from three (3) different clinical sites, seven (7) X100 with Full Field PBS devices (reference device), and three (3) candidate devices (X100HT). The sample slides represented a variety of clinical conditions that were included in the original 510(k) study. The study met predefined acceptance criteria including regression analysis for the four WBC cell types and platelets.

Cell Type	Total Observations	Total Observations in Reference Range	% Of Total Observations in Reference Range
Neutrophil	450	448	99.56%
Lymphocyte	450	449	99.78%
Variant Lymphocyte	450	444	98.67%
Monocyte	450	445	98.89%
Eosinophil	450	448	99.56%
Eosinophil	450	449	99.78%
Basophil	450	450	100.00%
Plasma Cell	450	447	99.33%
Immature Cell	450	447	99.33%
Blast	450	447	99.33%
NRBC	450	450	100.00%
Platelets	450	448	99.56%

Passing-Bablok Regression Results for WBC Differential

Cell Type	Intercept with 95% CI	Slope with 95% CI	Correlation coefficient
Neutrophil (%)	0.06 (-1.05, 1.36)	1.01 (0.97, 1.04)	0.990
Lymphocyte (%)	-0.16 (-0.59, 0.65)	1.02 (0.99, 1.03)	0.984
Monocyte (%)	0.16 (-0.33, 0.48)	1.03 (0.99, 1.10)	0.984
Eosinophil (%)	0.00 (-0.01, 0.03)	1.04 (0.97, 1.09)	0.935

Passing-Bablok Regression Results for PLT estimation

Cell Type	Intercept with 95% CI	Slope with 95% CI	Correlation coefficient
Platelets Estimation (10^3/µL)	0.72 (-7.18, 4.94)	1.02 (0.99, 1.08)	0.990

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.