October 2, 2020

Scopio Labs LTD.
% Yarmela Pavlovic
Regulatory Counsel
Manatt Health
1 Embarcadero Center, 30th Floor
San Francisco, California 94111

Re: K201301
Trade/Device Name: X100 with Full Field Peripheral Blood Smear (PBS) Application
Regulation Number: 21 CFR 864.5260
Regulation Name: Automated Cell-Locating Device
Regulatory Class: Class II
Product Code: JOY
Dated: May 15, 2020
Received: May 15, 2020

Dear Yarmela Pavlovic:

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,

Takeesha Taylor-Bell
Chief
Division of Immunology
and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201301

Device Name
X100 with Full Field Peripheral Blood Smear (PBS) Application

Indications for Use *(Describe)*

The X100 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.

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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510(k) SUMMARY

This 510(k) Premarket Notification Summary is prepared in accordance with 21 CFR 807.92.

I. Submitter Information

Sponsor Name:	Scopio Labs Ltd.
Sponsor Address:	Scopio Labs Ltd. 11 Tiomkin Street Tel Aviv 6578313 Israel
Sponsor Email:	info@scopiolabs.com
Contact Person:	Shahar Karny Director of Clinical AI Scopio Labs
Contact Email:	shahar@scopiolabs.com
Contact Telephone:	+972-54-6542164
Date Summary Prepared:	May 5, 2020

II. Device

Trade (Proprietary) Name:	X100 with Full Field Peripheral Blood Smear Application
Common (Usual) Name:	Full Field PBS, Scopio
Regulation Number:	21CFR864.5260
Regulation Name:	Automated cell-locating device
Regulatory Class:	II
Product Code:	JOY
Product Panel:	Hematology

III. Predicate Device

Predicate A

Device Name:	EasyCell Cell Locator
Device 510(k):	k092116
Manufacturer	Medica Corporation

Predicate B

Device Name:	Romanowsky stain manual light microscope process for cell classification
Device 510(k):	21CFR 864.3600 Class I exempted from pre-market notification procedure

IV. Device Description

X100 with Full Field Peripheral Blood Smear Application (Scopio's Full Field PBS) automatically locates and presents high resolution digital images from fixed and stained peripheral blood smears.
The user browses through the imaged smear to gain high-level general impressions of the sample.
In conducting white blood cells (WBC) differential, the user reviews the suggested classification of each automatically detected WBC, and may manually change the suggested classification of any cell.
In conducting red blood cells (RBC) morphology evaluation, the user can characterize RBC morphology on observed images.
In conducting platelets estimation, the user reviews each automatically detected platelet and the suggested platelet estimation, and may manually change the detections or the estimation.
The X100 with Full Field Peripheral Blood Smear Application is intended to be used by skilled users, trained in the use of the device and in the identification of blood cells.

V. Intended Use

The X100 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.

VI. Comparison of Technological Characteristics with the Predicate Devices

The X100 with Full Field Peripheral Blood Smear Application is substantially equivalent to its predicate devices, the EasyCell (K092116), and the manual light microscope. The subject device has the same intended use as the predicates in that all devices are intended to assist a qualified user in conducting evaluations of white blood cells, red blood cells and platelets within a fixed and stained peripheral blood smear. Additionally, the devices are also substantially equivalent with respect to technological characteristics. While the specific information provided by the subject device varies somewhat compared to the predicates, in the case of all devices the information provided must be interpreted and confirmed or adjusted by the trained user. Thus, these differences do not raise different questions of safety or effectiveness.
The similarities and differences between the subject device and the predicate devices are summarized in Table 1 below.

Table 1 Comparison of Characteristics with the Predicate Devices

Item	Manual light microscopic process	EasyCell k092116	Full Field PBS
Similarities			
Intended use	Intended to locate and display images of white cells, red cells, and platelets acquired from fixed and stained peripheral blood smears. For in vitro diagnostic use only. For professional use only	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.	Same as for EasyCell
Sample Type	Stained blood film glass slides of peripheral whole blood	Same	Same
Sample Preparation	Romanowsky stain	Same	Same
Analysis Technique: White Blood Cells	WBC are manually located, classified and counted by moving according to the battlement pattern (ensuring that each cell is counted only once).	WBC are located/counted by moving according to the battlement pattern (ensuring that each cell is counted only once). Cell images are analysed 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 suggested classification, and accepts or reclassifies the images.	Same as for EasyCell
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	Same
Daily QC	N/A	The QC procedure controls for slide preparation (both smearing and staining) and EasyCell performance. If the QC procedure does not pass, the operator must resolve the problem and rerun the QC before processing samples.	Same as for EasyCell

Item	Manual light microscopic process	EasyCell k092116	Full Field PBS
Differences			
Analysis Technique: Platelets	Platelets are manually located and estimated by moving according to the battlement pattern (ensuring that each cell is counted only once).	The device presents a series of images. The reviewers manually count and estimate the platelet concentration from the images according to a procedure in the User's Manual.	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.
Pre-classified WBC	N/A	Cell images are grouped into eight (8) categories: ● Neutrophils (Band or Segmented ● Lymphocytes ● Monocytes ● Eosinophils ● Basophils ● Nucleated Red Blood Cells ● Smudge cells ● Other (which is intended to hold morphologically abnormal cells.)	Cell images are grouped into eighteen (18) categories: • Band Neutrophils • Segmented Neutrophils • Lymphocytes • Atypical Lymphocytes • Large Granular Lymphocytes • Aberrant Lymphocytes • Monocytes • Eosinophils • Basophils • Promyelocyte • Metamyelocytes • Myelocytes • Blasts • Plasma Cells • Nucleated Red Blood Cells • Unclassified • Smudge cells • Dirt
High-Resolution Image Acquisition	Manual image viewing through a 100X magnification lens and immersion oil.	Fully automated scan and image acquisition. Captures images at 10X resolution to locate certain cells and then capture images of those cells using a 100X magnification lens and immersion oil.	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.

VII. Performance Data

Method Comparison

A Method Comparison was conducted to compare the results achieved by trained examiners using the X100 with Full Field Peripheral Blood Smear Application (the Test Method) to the results achieved by using a manual light microscope.

A total of 645 specimens were collected and analyzed at three sites. 335 specimens were from normal (healthy) subjects and 310 were from subjects with specific disease conditions. Slides were prepared from each specimen. The slides were randomly selected, blinded and read by two examiners at each site.

White Blood Cells

Table 2 WBC Correlation between Reference Method and Test Method

Results from Deming regression analyses on readings between subject device and manual microscope are as follows:

Cell Type	Correlation Coefficient (r)	Slope	Intercept
Neutrophil (%)	98%	1.00	0.39
Lymphocyte (%)	96%	0.99	-0.51
Monocyte (%)	95%	0.94	-0.15
Eosinophil (%)	98%	0.89	0.00

Table 3 WBC differential efficiency, sensitivity and specificity.

Measurements of **distributional WBC** (Band and Segmented Neutrophil, Monocyte, Lymphocyte and Eosinophil) and **morphological WBC** (Immature Granulocyte, Variant Forms Lymphocyte, Blast, NRBC and Plasma cell) between subject and manual microscope. In parenthesis are the calculated 95% confidence intervals.

	Morphological Abnormality	Distributional Abnormality	Overall
Efficiency	96.82% (96.12% to 97.43%)	95.75% (94.95% to 96.46%)	96.29% (95.77% to 96.76%)
Sensitivity	85.46% (80.19% to 89.78%)	88.83% (85.94% to 91.31%)	87.86% (85.38% to 90.06%)
Specificity	97.79% (97.16% to 98.31%)	97.43% (96.70% to 98.03%)	97.62% (97.16% to 98.02%)

Red Blood Cells

Table 4 Red Blood Cells Morphology Evaluation

Results of overall agreement for RBC morphology evaluation are as follows:

RBC Morphology	Overall Agreement with 95% CI
Overall	99.77% (99.71% to 99.83%)

RBC Morphology Group	Overall Agreement with 95% CI
Color	99.49% (99.14% to 99.73%)
Shape	99.77% (99.68% to 99.84%)
Size	99.61% (99.36% to 99.78%)
Inclusions	100.00% (99.93% to 100.00%)
Arrangement	96.65% (95.52% to 97.57%)

Platelets

Table 5 Platelet estimation correlation between reference method and test method

Results from Deming regression analyses on readings with subject and manual microscope are as follows:

Cell Type	Correlation Coefficient (r)	Slope	Intercept
Platelets Estimation (103/µL)	94%	1.03	-10.31

Table 6 Platelet estimation efficiency, sensitivity and specificity

	Overall
Efficiency	94.89% (92.78% to 96.53%)
Sensitivity	90.00% (83.51% to 94.57%)
Specificity	96.28% (94.11% to 97.82%)

All method comparison testing met acceptance criteria.

Precision (Repeatability & Reproducibility)

Repeatability

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

A 20x2x2 repeatability study for the analyses of white blood cells differential and platelets estimation was conducted using a single instrument at a single site with 15 selected test samples. Over the course of 20 testing days, 2 daily runs were performed using 2 replicas. The selected samples represented different clinical conditions, to include all automatically located and pre-classified cell types. In total, 1,200 scans were analyzed.

For each tested sample, SD and %CV were estimated for the four variance components: repeatability, between-run (within-day), between-day and within-laboratory. The results met the predefined acceptance criteria.

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 and platelets estimation was performed across 3 different sites. The study was conducted at each site, with 10 test samples, for 5 testing days, using 5 replicas scanned with the local device. The selected samples represented different clinical conditions, to include all automatically located and pre-classified cell types. In total, 750 scans were analyzed.

For each tested sample, SD and %CV were estimated for the five variance components: repeatability, between day (within-site), within-laboratory, between site, and reproducibility. The results met the predefined acceptance criteria.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's guidance. 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.

VIII. Conclusion

Study results demonstrated that X100 with Full Field Peripheral Blood Smear Application is substantially equivalent to the predicate device.