June 27, 2025

Scopio Labs Ltd.
% Randy Prebula
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K243144
Trade/Device Name: X100 with Full Field Peripheral Blood Smear (PBS) Application
X100HT 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 28, 2025
Received: May 28, 2025

Dear Randy Prebula:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Takeesha Taylor-Bell
Deputy Director
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)*
K243144

Device Name
X100 with Full Field Peripheral Blood Smear (PBS) Application
X100HT with Full Field Peripheral Blood Smear (PBS) Application

Indications for Use *(Describe)*

The X100/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.

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. 10 Hasharon Street Tel Aviv 6618502 Israel
Sponsor Email:	regulation@scopiolabs.com
Contact Person:	Ifat Raved VP, Compliance and Regulatory Affairs Scopio Labs
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Contact Telephone:	+972-50-8447463
Date Summary Prepared:	September 29, 2024

II. Device

Trade (Proprietary) Name:	X100 / X100HT 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

Device Name:	X100 / X100HT with Full Field Peripheral Blood Smear Application
Device 510(k):	K201301, K220013
Manufacturer	Scopio Labs Ltd.

IV. Device Description

The X100 / X100HT with Full Field Peripheral Blood Smear (PBS) Application ("Full Field PBS") is a digital cell morphology solution, presenting high resolution digital images of fixed and stained microscopy Peripheral Blood Smears. The Full Field PBS was previously cleared by the Agency on October 2, 2020, throughout the review of K201301 and on May 3, 2022, throughout the review of K220013. The system automatically locates and presents images of peripheral blood cells and streamlines the PBS analysis process with a review workflow composed of four steps: (1) full field review, (2) white blood cells (WBC) review (DSS for WBC Pre-Classification is available), (3) red blood cells (RBC) review and (4) platelet review (DSS for platelet estimation is available).

Under the proposed modification, subject of this 510(k) submission, additional DSS component is added to the RBC and Platelet review steps. Concerning RBC analysis, system-suggested RBC morphological pre-gradings are added as proposed DSS to the user by means of a dotted line around a suggested grading selection box. Notably, the user is still required to review the slide and actively mark the final grading, exactly as performed in the cleared workflow review.

The same approach is used with regard to the update to the platelet review step; A system-suggested platelet clump indication is presented to the user by means of a dotted line around a selection box. Notably, the user is still required to manually mark whether platelet clumps were detected, exactly as currently performed in the cleared workflow review.

The changes under discussion do not affect the cleared indications for use or intended use; the user's workflow of scanning and analyzing peripheral blood smears using the Full Field PBS Application remains otherwise unchanged as well.

Moreover, these changes do not affect the Full Field PBS reviewing workflow, which is performed in a manner identical to the reviewing process cleared in K201301 and K220013, with one difference, which is a dotted line appearing around suggested RBC morphology gradings and around platelet clumps indication box. Regardless of the newly introduced changes, the user is still required to actively grade the different characteristics to be included in the final report.

V. Intended Use – X100 / X100HT with Full Field PBS Application

The X100/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.

VI. Summary of Technological Characteristics

The subject device is substantially equivalent to its predicate device, the cleared X100 / X100HT with Full Field PBS (K201301, K220013). The subject device has the same intended use and intended user as the predicate, both 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 smears. In addition, the technological characteristics of the subject device are also equivalent to the predicate, hence the subject device does not raise different questions of safety and effectiveness; The subject and predicate device are based on the same technological elements, as described in the paragraph to follow.

VII. Comparison of Technological Characteristics with the Predicate Device

The modified X100 / X100HT with Full Field Peripheral Blood Smear (PBS) Application is substantially equivalent to its predicate device, the cleared X100 / X100HT with Full Field Peripheral Blood Smear (PBS) Application (K201301, K220013). The subject device has the same intended use, and very similar technological characteristics and principles of operation. Both subject device and predicate 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. The indications for use are identical to the predicate device. Additionally, the devices are also very similar with respect to technological characteristics. While additional DSS were added to the subject device's RBC and platelet review steps, the information provided must be confirmed or adjusted by the user, who must actively mark the appropriate selection. Thus, this difference does 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.

Similarities		
Item	**Predicate Device**	**Modified Device**
Intended use	**X100 with Full Field PBS Application** The X100 with Full Field Peripheral Blood Smear (PBS) 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. **X100HT with Slide Loader with Full Field PBS Application** The X100HT with Full Field Peripheral Blood Smear (PBS) 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.	Same Same

Similarities		
Item	**Predicate Device**	**Modified Device**
Intended User	Skilled users, trained in the use of the device and in the identification of blood cells.	Same
Sample Type	Stained blood film glass slides of peripheral whole blood	Same
Sample Preparation	Romanowsky stain	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 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
Analysis Technique: Platelets estimation	Platelets 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 detect platelets. The user reviews the suggested estimate of the platelet concentration, and accepts or modifies the result.	Same
Quality Control	The daily QC involves testing a standard blood smear slide. 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.	Same

Similarities		
Item	**Predicate Device**	**Modified Device**
Dimensions	**X100** Width 32cm Length 32cm Height 35cm **X100HT** Width 39cm Length 42cm Height 55cm	Same
Weight	**X100** 14Kg **X100HT** 33Kg	Same
Compatible Platforms	X100 / X100HT	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
Power Source	120/100 – 240V, 1.5A, 50 – 60 Hz	Same

Differences		
Item	**Predicate Device**	**Modified Device**
Analysis Technique: Red Blood Cells	The device presents an overview image. The examiner manually grades RBC morphology from the image.	The device presents an overview image. The system presents to the user RBC morphology grading suggestions. The examiner manually grades RBC morphology from the image.
Analysis Technique: Platelets Clump presence	The device presents an overview image. The examiner manually reports if platelet clumps are present in the smear.	The device presents an overview image. The system presents to the user a suggestion whether platelet clumps were detected. The examiner manually reports if platelet clumps are present in the smear.

Table 1, Comparison of Characteristics with the Predicate Devices

VIII. Performance Data

The Following performance data were provided in support of the substantial equivalence determination.

Clinical Evaluation - Method Comparison Study

The company conducted a method comparison study in order to verify the safety and effectiveness of the modification to the Full Field PBS Application. A total of 1200 anonymized PBS slides were collected from the laboratory routine workload of three medical centers.

Method Comparison Study – Results

Category	Overall Agreement	PPA	NPA
RBC Color	**97.88%** (97.29% to 98.42%)	**98.33%** (97.48% to 99.10%)	**97.61%** (96.81% to 98.33%)
RBC Inclusions	**97.90%** (97.50% to 98.27%)	**86.73%** (81.66% to 91.23%)	**98.41%** (98.06% to 98.78%)
RBC Shape	**96.22%** (95.92% to 96.50%)	**95.35%** (94.50% to 96.12%)	**96.40%** (96.06% to 96.71%)
RBC Size	**95.58%** (95.06% to 96.13%)	**99.42%** (99.03% to 99.75%)	**92.72%** (91.82% to 93.70%)
PLT Clumping	**87.08%** (85.25% to 88.92%)	**86.11%** (82.13% to 89.91%)	**87.39%** (85.39% to 89.39%)

The results met the pre-defined acceptance criteria; The study's results therefore support the safety and effectiveness of the modification to the Full Field PBS Application.

Precision Studies (Repeatability & Reproducibility)

The company conducted precision studies, composed of a repeatability study and a reproducibility study, according to CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition.

Repeatability

A 20x2x2 repeatability study for the analysis of RBC-DSS and platelet clumps indication DSS was conducted using 27 test samples, representing different RBC morphological features at various levels of severity as well as presence PLT clumping.

The repeatability study results met the pre-defined acceptance criteria.

Reproducibility

A 3x5x5 reproducibility study for the analysis of RBC-DSS and platelet clumps indication DSS was conducted using 16 test samples, representing different RBC morphological features at various levels of severity as well as presence PLT clumping.

The reproducibility study results met the pre-defined 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 is subject to the Basic Documentation Level as defined in FDA's *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices* (June 14, 2023), because a failure or flaw in the software would not present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use.

IX. Conclusion

Study results, as well as software V&V and risk analysis activities demonstrate that the modified Full Field PBS Application is substantially equivalent to the predicate device, the cleared Full Field PBS Application (K201301, K220013).