May 3, 2022

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

Re: K220013
Trade/Device Name: X100HT with Slide Loader 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: January 4, 2022
Received: January 4, 2022

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 (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, 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)*

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

Indications for Use *(Describe)*
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.

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 Ha'Sharon Street Tel Aviv 6578313 Israel
Sponsor Email:	info@scopiolabs.com
Contact Person:	Shahar Karny COO Scopio Labs
Contact Email:	shahar@scopiolabs.com
Date Summary Prepared:	December 23, 2021

II. Device

Trade (Proprietary) Name:	X100HT with Full Field Peripheral Blood Smear (PBS) Application
Regulation Number:	21CFR§864.5260
Regulation Name:	Automated cell-locating device
Regulatory Class:	II
Product Code:	JOY
Product Panel:	Hematology

III. Predicate Device

Predicate A

Device Name:	X100 with Full Field Peripheral Blood Smear (PBS) Application
Device 510(k):	K201301
Manufacturer	Scopio Labs

IV. Device Description

X100HT with Full Field Peripheral Blood Smear (PBS) Application 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 X100HT with Full Field PBS 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 platelets estimation and may manually change the detections or the estimation.

The X100HT with Full Field PBS enables efficient slide loading by providing three cassettes, each can be loaded with up to ten peripheral blood smear slides. The slide loader automatically adds mounting media and coverslips to the slides and loads them into the X100 for scanning and analysis.

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.

V. Intended Use

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.

VI. Comparison of Technological Characteristics with the Predicate Devices

The X100HT with Full Field Peripheral Blood Smear (PBS) Application is substantially equivalent to its predicate device, the X100 with Full Field Peripheral Blood Smear (PBS) Application (K201301). The subject device has the same intended use as the predicate in that 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 smear. Additionally, both devices are also substantially equivalent with respect to technological characteristics. In both the X100HT and X100 with Full Field PBS, the X100 hardware is identical. Moreover, the Full Field PBS software application module responsible for the imaging and analysis is identical. The main differences between the subject device and the predicate are the addition of a Slide Loader add-on which encapsulates the X100, additional slide locks were added to the X100 tray, and a minor modification to the Full Field PBS application module responsible for scan initiation was implemented. The Slide Loader replaces required manual user actions of mounting media and slide cover-slipping and slide-tray loading.

The additional tray locks were introduced to verify reliable slide positioning. The modified Full Field PBS application module enables the three-cassette workflow rather than the three slides workflow. As with the predicate, the preparation of the stained blood smear and bar coding of the slide are identical for the X100HT and are still externally prepared by the user, either manually or by third party devices. While the manual steps of mounting media and coverslip addition were replaced by a mechanical module, and the minor change of scan initiation interface, the analysis information provided by both devices uses the identical technology that was originally 510(k)-cleared and must be interpreted and confirmed or adjusted by the trained user. Thus, the minor 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 of the X100HT with the Predicate Device

Item	X100HT with Full Field PBS	X100 with Full Field PBS (Predicate, K201301)
Intended Use	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
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 fixated 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
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.
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	WBC 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 suggested classification, and accepts or reclassifies the images.	Same
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

Scopio Labs
Cell Morphology at Scale

Item	X100HT with Full Field PBS	X100 with Full Field PBS (Predicate, K201301)
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 • Promyelocyte • Metamyelocytes • Myelocytes • Blasts • Plasma Cells • Nucleated Red Blood Cells • Unclassified • Smudge cells • Dirt	Same
Dimensions	Width 39cm Length 42cm Height 55cm	Width 32cm Length 32cm Height 35cm
Weight	33 Kg	14 Kg
Power Source	120/100 – 240V, 1.5A, 50 – 60 Hz	Same

VII. Testing

Software and Hardware Verification and Validation Testing

A comprehensive risk analysis was conducted and documentation was provided as recommended by FDA's guidance. Verification and validation testing was conducted and documentation was updated. The 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.

EMC Testing

The X100HT with Full Field PBS successfully passed EMC testing in compliance with *IEC 60601-1-2 4th edition (2014) standard and FCC CFR 47 Part 15 Subpart B, ANSI C63.4:2014*.

Safety Testing

The X100HT with Full Field PBS successfully passed Safety testing in compliance with *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 equipment* as well as *IEC / EN 61010-1: 2010 (3rd Edition) Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements and IEC 62471:2006 / EN 62471:2008 Photobiological safety of lamps and lamp systems.*

VIII. Conclusion

Risk analysis and testing results demonstrated that X100HT with Full Field PBS is substantially equivalent to the predicate device.