March 22, 2024

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

Re: DEN230034
Trade/Device Name: X100 with Full Field Bone Marrow Aspirate (BMA) Application, X100HT with Full Field Bone Marrow Aspirate (BMA) Application
Regulation Number: 21 CFR 864.5261
Regulation Name: Automated cell-locating device for bone marrow aspirate
Regulatory Class: Class II
Product Code: SAL
Dated: April 28, 2023
Received: April 28, 2023

Dear Randy Prebula:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the X100 with Full Field Bone Marrow Aspirate (BMA) Application, X100HT with Full Field Bone Marrow Aspirate (BMA) Application, a prescription device with the following indications for use:

> X100 with Full Field BMA Application:
> The X100 with the Full Field Bone Marrow Aspirate (BMA) Application is an automated cell locating device, intended for in vitro use only. The Full Field BMA application automatically locates and presents images of hematopoietic cells to trained operators for visual evaluation of Romanowsky stained bone marrow aspirate (BMA) smears. The Full Field BMA application assists trained operators to perform bone marrow smear quality assessment, blast cell, plasma cell, and M:E ratio estimation. A qualified operator must review, confirm or modify classification of each cell according to type, and verify results before finalizing and releasing the report.
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> The X100 with the Full Field Bone Marrow Aspirate (BMA) application presents images of Prussian Blue stained BMA smear.
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> X100HT with Full Field BMA Application:
> The X100HT with the Full Field Bone Marrow Aspirate (Full Field BMA) Application is an automated cell locating device, intended for in vitro use only. The Full Field BMA application

> automatically locates and presents images of hematopoietic cells to trained operators for visual evaluation of Romanowsky stained bone marrow aspirate (BMA) smears. The Full Field BMA application assists trained operators to perform bone marrow smear quality assessment, blast cell, plasma cell, and M:E ratio estimation. A qualified operator must review, confirm or modify classification of each cell according to type, and verify results before finalizing and releasing the report.
>
> The X100HT with the Full Field Bone Marrow Aspirate (BMA) application presents images of Prussian Blue stained BMA smear.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the X100 with Full Field Bone Marrow Aspirate (BMA) Application, X100HT with Full Field Bone Marrow Aspirate (BMA) Application, and substantially equivalent devices of this generic type, into Class II under the generic name automated cell-locating device for bone marrow aspirate.

FDA identifies this generic type of device as:

> **Automated cell-locating device for bone marrow aspirate**. An automated cell-locating device for bone marrow aspirate is an in vitro diagnostic device intended for prescription use that automatically locates and presents images of hematopoietic cells on a bone marrow aspirate smear obtained from patients being evaluated for hematologic diseases. The device assists operators to identify and classify each cell according to type.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On April 28, 2023, FDA received your De Novo requesting classification of the X100 with Full Field Bone Marrow Aspirate (BMA) Application, X100HT with Full Field Bone Marrow Aspirate (BMA) Application. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the X100 with Full Field Bone Marrow Aspirate (BMA) Application, X100HT with Full Field Bone Marrow Aspirate (BMA) Application into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the X100 with Full Field Bone Marrow Aspirate (BMA) Application, X100HT with Full Field Bone Marrow Aspirate (BMA) Application can be classified in class II with the establishment of

special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	Mitigation Measures
Clinical action based on false positive results may lead to misdiagnosis, inappropriate patient management, or unnecessary treatments.	Certain design verification and validation, including documentation of certain analytical studies and clinical studies. Certain labeling information, including limitations.
Clinical action based on false negative results may lead to delayed diagnosis, missed diagnosis, or delay in treatment.	Certain design verification and validation, including documentation of certain analytical studies and clinical studies. Certain labeling information, including limitations.

In combination with the general controls of the FD&C Act, the automated cell-locating device for bone marrow aspirate is subject to the following special controls:

(1) Design verification and validation must include the following:

(i) Detailed documentation of data that demonstrates device clinical performance for all intended clinical uses, including all indications for use. These data must include results from performance testing that compares the clinical performance of the device versus conventional manual microscopy in the intended use population. The operators must be comprised of intended users with appropriate training in bone marrow aspirate review.

(ii) Documentation of data demonstrating the precision performance for each reported parameter (test output). Precision performance must be evaluated using intended use clinical specimens demonstrating the spectrum of device outputs, including using specimens throughout the expected range and with values near medical decision points for each reported parameter (test output), as appropriate.

(iii) Documentation of expected (reference) values for test output demonstrated by testing a statistically justified number of samples from apparently healthy normal individuals, as applicable.

(iv) Documentation that the device results are reported to the user for each reported parameter from the images prior to operator review (pre-classified automated device results) along with the data after operator review (reclassification or modification by user).

(2) The labeling required under 21 CFR 809.10(b) must include limiting statements indicating, as applicable:

(i) That intended users should exercise professional judgment and examine the slides by conventional microscopy if there is doubt about the quality of the digital images provided by the device.

(ii) Any specific procedures and safeguards (e.g., quality control measures) that the intended users must follow to assure the validity of the interpretation of images obtained using the device.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the automated cell-locating device for bone marrow aspirate for they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Dinuka DeSilva at Dinuka.DeSilva@fda.hhs.gov.

Sincerely,

Takeesha Taylor-bell -S

for

Lea R. Carrington
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