August 16, 2023

PixCell Medical Technologies, Ltd.
% Erika Ammirati
President
Ammirati Regulatory Consulting
575 Shirlynn Court
Los Altos, California 94022

Re: K222148
Trade/Device Name: HemoScreen Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: March 29, 2023
Received: March 30, 2023

Dear Erika Ammirati:

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 -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K222148

Device Name
HemoScreen Hematology Analyzer

Indications for Use *(Describe)*
The HemoScreen is a point-of-care (POC) automated hematology analyzer intended for the enumeration and classification of the following parameters in capillary and venous whole blood (K2EDTA anticoagulated): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, NEUT%, NEUT#, LYMP%, LYMP#, MONO%, MONO#, EO%, EO#, BASO%, and BASO#. The HemoScreen is for in vitro diagnostic use in clinical laboratories and/or POC settings for adults and children at least 2 years of age.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K222148.

807.92 (a)(1): Name: PixCell Medical Technologies, Ltd.
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Phone: +972-4-9593516
Email: yaara@pixcell-medical.com
Contact: Yaara Ben-Yosef, PhD

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name: HemoScreen Hematology Analyzer

Common Name: Automated differential cell counter

Classification: 21 CFR 864.5220

807.92 (a)(3): Identification of the legally marketed predicate devices

HemoScreen Hematology Analyzer (PixCell Medical Technologies, Ltd), cleared under K180020.

807.92 (a)(4): Device Description

HemoScreen is a point of care (POC), automated hematology analyzer that provides 20 common CBC parameters, including a 5-part leukocyte (WBC) differential, in capillary and venous whole blood samples. The HemoScreen analyzer (reader) is a tabletop device that is designed to use with a disposable reagent Cartridge. In addition to the Cartridge, the system includes a disposable Sampler with two glass capillaries which is used to collect the blood sample and then transfer it to the Cartridge.

Once the Cartridge is inserted into the reader, there are no further procedural steps; blood is expelled from the capillaries (Sampler) into the reagent compartments (Cartridge). The reader then mixes the blood sample with the reagents by alternately pressing compressible portions of the Cartridge, eventually causing the suspension of cells to flow into the microfluidic chamber. Cells flowing in the microfluidic chamber focus into a single-cell plane due to a patented physical phenomenon known as viscoelastic focusing.

The reader then captures images of the focused cells and analyzes them in real time using machine vision algorithms. When analysis is complete, the results are displayed to the user on the reader's touch screen and may be printed to an adjacent printer or exported to a USB flash drive. The Cartridge is ejected by the analyzer after analysis, and can then be safely disposed of, as the reagents and blood sample remain within the Cartridge.

The basic staining and microscopic image analysis performed by HemoScreen closely resembles the traditional blood smear and the hemocytometer counting chamber. Leukocytes are classified based on their staining properties and morphology, whereas absolute counts are obtained by counting the cells contained in a chamber of predetermined volume. Test results are obtained within six (6) minutes and the results are saved.

Quality Control: Commercial 3-level liquid quality controls, PIX-CBC Hematology Controls, are recommended for use with the HemoScreen. These controls cover all the tested parameters and are sampled the same way whole blood is sampled.

Software: The HemoScreen software displays an intuitive, simple-to-use user interface that is operated via the touch screen. The software is responsible for operating the device, performing the measurements, and recording the results.

807.92 (a)(5): Intended Use

The HemoScreen is a point-of-care (POC) automated hematology analyzer intended for the enumeration and classification of the following parameters in capillary and venous whole blood (K_2EDTA anticoagulated): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, NEUT%, NEUT#, LYMP%, LYMP#, MONO%, MONO#, EO%, EO#, BASO%, and BASO#. The HemoScreen is for in vitro diagnostic use in clinical laboratories and/or POC settings for adults and children at least 2 years of age.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

The following chart describes similarities and differences between HemoScreen and the predicate.

Comparison	ON-TEST HemoScreen with direct fingerstick sampling	PREDICATE HemoScreen with indirect fingerstick sampling (K180020)
Intended Use	Automated hematology analyzer	Same
Parameters Measured	• Red Blood Cells (RBC), • White Blood Cells (WBC), • Platelets (PLT), • Hemoglobin (HGB), • Hematocrit (HCT), • Mean Corpuscular (erythrocyte) Volume (MCV), • Mean Cell (erythrocyte) Hemoglobin (MCH), • Mean Cell (erythrocyte) Hemoglobin Concentration (MCHC), • Red Blood Cell Distribution Width (RDW)-CV • Mean Platelets Volume (MPV), • Neutrophils (NEUT; #/%), • Monocytes (MONO; #/%),	Same

Comparison	ON-TEST HemoScreen with direct fingerstick sampling	PREDICATE HemoScreen with indirect fingerstick sampling (K180020)
	• Lymphocytes (LYMP; #/%), • Eosinophils (EO; #/%) and • Basophiles (BASO; #/%)	
Class	Class II	Same
Regulation Number	21 CFR 864.5220	Same
Product Code	GKZ	Same
FDA Branch	Hematology	Same
Throughput	10 samples/hour	Same
Test Principle	The HemoScreen uses a novel focusing method called viscoelastic focusing which causes the cells to perfectly align into a plane. High resolution microscopic images are taken of the flowing cells. Each image is analyzed using machine vision algorithms and the different cell types are differentiated and counted. WBCs are stained prior to analysis so as to enable differentiation between their subtypes and abnormal cells. HGB is calculated based on the optical density measured on intact individual cells.	Same
Calibration	Factory calibrated	Same
Sample Type-venous	K_2EDTA anticoagulated whole blood	Same
Sample Type-fingerstick	Direct and indirect *Direct*: Capillary blood from fingertip drawn directly into Sampler. *Indirect:* Capillary blood from fingertip delivered to microtube, then transferred into Sampler	Indirect, only
Sample Volume	40µL	Same

807.92 (b)(1): Brief Description of Nonclinical Data- no changes from K180020

Limit of Blank

Please refer to the 510(k) Summary for K180020.

Limits of Detection and Quantitation

Please refer to the 510(k) Summary for K180020.

Linearity

Please refer to the 510(k) Summary for K180020.

Repeatability of Venous Samples (internal and external operators)

Please refer to the 510(k) Summary for K180020.

Reproducibility of QC Materials

Please refer to the 510(k) Summary for K180020.

Interference

Please refer to the 510(k) Summary for K180020.

Reference Intervals- Adult Males and Females (CLSI EP28-A3C)

Please refer to the 510(k) Summary for K180020.

807.92 (b)(2): Brief Description of Clinical Data-

No changes from K180020 for venous sampling and indirect capillary sampling into a K_2EDTA microtube. The data in this section reflect the comparisons between direct capillary sampling (on-test), and indirect capillary sampling (predicate).

Comparisons between Direct Capillary Sampling and Indirect Capillary Sampling.

A comparison HemoScreen to HemoScreen study was performed where results from direct sampling of fingerstick blood into the Sampler were compared to results from indirect sampling, where fingerstick blood was first collected into a K_2EDTA microtube, and then transferred to the Sampler. This was a prospective clinical study that included 42 subjects and matched fingerstick collections. The data were evaluated by Passing-Bablok regression and Pearson's correlation for all 20 parameters, and the summarized data are provided below.

Passing-Bablok Regression Data and Pearson Correlation

Parameter	N	Result Range (Indirect)	Intercept [95% CI]	Slope [95% CI]	Pearson Correlation
WBC (10^3/µL)	42	4.54-12.52	-0.216 [-0.893, 0.412]	1.028 [0.955, 1.108]	0.978
RBC (10^6/µL)	42	4.14-5.78	0 [-0.401, 0.498]	0.994 [0.881, 1.078]	0.97
HGB (g/dL)	42	11.84-17.12	-0.749 [-2.348, 1.097]	1.048 [0.913, 1.156]	0.969
HCT (%)	42	35.76-50.11	-1.77 [-7.048, 3.527]	1.032 [0.901, 1.157]	0.967
MCV (fL)	42	76.6-93.84	1.013 [-2.325, 3.887]	0.988 [0.954, 1.025]	0.994
MCH (pg)	42	24.67-32.98	-0.191 [-0.907, 0.605]	1.007 [0.981, 1.032]	0.998
MCHC (g/dL)	42	32.2-35.83	-1.519 [-4.767, 1.859]	1.047 [0.949, 1.143]	0.961
RDW (%)	42	11.64-14.16	-0.25 [-0.876, 0.266]	1.019 [0.977, 1.068]	0.991
PLT (10^3/µL)	42	142.4-399.6	3.646 [-16.602, 21.01]	0.963 [0.894, 1.051]	0.979
MPV (fL)	42	9.18-13.46	0.572 [-1.036, 1.837]	0.949 [0.832, 1.113]	0.92
NEUT (10^3/µL)	42	2.19-7.95	-0.221 [-0.531, 0.062]	1.049 [0.995, 1.109]	0.984
LYMP (10^3/µL)	42	1.51-4.17	-0.153 [-0.562, 0.251]	1.075 [0.925, 1.273]	0.953
MONO (10^3/µL)	42	0.27-0.86	-0.087 [-0.256, 0.023]	0.996 [0.796, 1.358]	0.825
EO (10^3/µL)	42	0.04-0.53	-0.021 [-0.032, -0.005]	1.017 [0.945, 1.081]	0.988
BASO (10^3/µL)	42	0.01-0.07	0.003 [-0.01, 0.012]	1.225 [0.842, 1.659]	0.598
NEUT (%)	42	43.75-68.8	-2.615 [-11.774, 4.007]	1.05 [0.941, 1.194]	0.957
LYMP (%)	42	19.95-45.05	-1.418 [-4.219, 1.404]	1.073 [0.983, 1.162]	0.969
MONO (%)	42	3.95-11.25	-2.108 [-3.977, -0.95]	1.147 [0.985, 1.459]	0.823
EO (%)	42	0.7-7.3	-0.27 [-0.429, -0.028]	1.029 [0.968, 1.097]	0.987
BASO (%)	42	0.1-0.7	-0.075 [-0.3, 0.15]	1.5 [1, 2]	0.614

CI = confidence interval

Precision of Direct Capillary Sampling

Twenty-three (23) subjects were enrolled for the direct capillary precision study. Two capillary punctures were performed on each subject, one puncture by each of two operators. The fingersticks were done on the same hand, with one operator collecting blood using the HemoScreen Sampler from one finger and completing the test, and the other operator collecting blood using the HemoScreen Sampler from another finger and completing the test. The operator order was randomized to counteract order effects, and the two punctures were done within 10 minutes of each other. One HemoScreen analyzer and multiple Cartridge lots were used for testing. Neither operator was aware of the test results from the other operator. Precision in capillary blood was shown to be adequate.

807.92 (b)(3): Conclusions from Nonclinical and Clinical Data

The conclusions drawn from the updated clinical data demonstrate that the device is safe and effective for its intended use.