May 2, 2024

PixCell Medical Technologies
Marcia L.Zucker
Regulatory Consultant to PixCell Medical Technologies, Ltd.
Zivd LLC
62 Pollard
Plaistow, New Hampshire 03865-2532

Re: K240636
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: February 22, 2024
Received: March 6, 2024

Dear Marcia L.Zucker:

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.

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,

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)*
K240636

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 K240636.

807.92 (a)(1): Name: PixCell Medical Technologies, Ltd.
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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 K222148.

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 less than 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	HemoScreen (K240636)	HemoScreen (K222148)
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; #/%), Lymphocytes (LYMP; #/%), Eosinophils (EO; #/%) and	Same

Comparison	HemoScreen (K240636)	HemoScreen (K222148)
	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. Hb is calculated based on the optical density measured on intact individual cells.	Same
Calibration	Factory calibrated	Same
Sample Type	Anticoagulated whole blood	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 microtainer, then transferred into Sampler	Same
Sample Volume	40µl	Same
Analytical Measuring Range (AMR) for WBC and PLT	WBC: 0.25-95 x 10^3/µl PLT: 7-988 x 10^3/µl	WBC: 0.5-80 x 10^3/µl PLT: 20-800 x 10^3/µl

807.92 (b)(1): Brief Description of nonclinical tests

Limit of Blank- (Reference CLSI EP17-A2 and CLSI H26-A2)

Five residual normal venous blood samples (from both morphological and cell distribution aspects) were centrifuged to deplete the plasma supernatant of RBCs, WBCs and PLTs. These processed samples were separated to clean neutral tubes with no additives and were assayed on HemoScreen devices. The parameters under evaluation were WBC, and PLT.

The limit of blank was determined by the 95th percentile of the distribution of the study variable, and the data are summarized below.

Summary Limit of Blank for WBC, and PLT for the HemoScreen

Parameter	LoB
WBC	0.12 x 10^3/µL
PLT	0.52 x 10^3/µL

Limits of Detection and Quantitation

For the LoDs and LoQs, five residual blood samples were diluted to low target concentration, and measured by the comparative method. Each of the processed samples was assayed on each of the HemoScreen devices. The LoDs were determined mathematically both from the LoBs and by HemoScreen testing.
The LoQs were defined as the lowest concentration in which pre-determined total error (TE) accuracy goals, as compared to the laboratory reference method, were satisfied. All TE goals were met (TEs were less than the goals), and the LoD and LoQ for the five parameters are shown below.

LoD and LoQ Summaries

Parameter	Units	LoD	LoQ
WBC	x 10^3/µL	0.23	0.23
PLT	x 10^3/µL	2.73	2.73

Linearity (CLSI H26-A2 and CLSI EP06-2nd edition)

The HemoScreen Linearity study was conducted at PixCell Medical, Israel. The study was performed in accordance with CLSI EP06. To cover the ranges the linearity of WBC and PLT was determined using serial dilutions prepared from the commercial linearity controls ("PIX-LINE"). Each level was measured in replicates on a single HemoScreen analyzer.

WBC and PLT parameters were confirmed to be linear across all tested points across the measuring ranges. The new ranges are presented in the table below.

Measurand	Linearity	Final AMR
WBC (10^3/µl)	0.25-95.0	0.25-95.0
PLT (10^3/µl)	7.0-988.0	7.0-988.0

Repeatability of Venous Samples (internal and external operators)

Please refer to the 510(k) Summary for K222148.

Repeatability of Capillary Samples from Direct Fingerstick

Please refer to the 510(k) Summary for K222148.

Reproducibility of QC Materials

Please refer to the 510(k) Summary for K222148.

Interference

Please refer to the 510(k) Summary for K222148.

Whole Blood Stability

Please refer to the 510(k) Summary for K222148.

Carry-Over

Not applicable

807.92 (b)(2): Brief Description of Performance Validation Data

Comparisons between venous sampling (on-test), and Sysmex (predicate).

A method comparison study was conducted to assess the performance of the HemoScreen with the extended linear ranges compared to the Sysmex XN. The objective of the study was to demonstrate that HemoScreen remains substantially equivalent to the Sysmex® XN-Series (XN-10, XN-20) Automated Hematology Analyzers (K112605) with the extended PLT and WBC ranges. 232 residual whole blood venous samples that span the HemoScreen extended linear ranges were selected. The data were evaluated by Passing-Bablok regression and Pearson's correlation for all 20 parameters, and the summarized data are provided below. The study was conducted in accordance with CLSI guideline H26-A.

Passing-Bablok regression and Pearson's correlation of HemoScreen vs. Sysmex XN

Parameter	Result Range (HemoScreen)	Correlation Coefficient (r)	Intercept	Lower 95% CI	Upper 95% CI	Slope	Lower 95% CI	Upper 95% CI
WBC (10^3/µL)	0.29-94.77	0.995	-0.034	-0.102	0.023	0.999	0.990	1.010
RBC (10^6/µL)	1.91-7.13	0.997	0.023	-0.015	0.063	0.998	0.988	1.009
HGB (g/dL)	5.65-20.72	0.995	-0.006	-0.153	0.137	0.993	0.982	1.005
HCT (%)	16.42-62.73	0.990	-0.180	-0.816	0.385	1.006	0.991	1.022
MCV (fL)	53.33-111.47	0.928	1.818	-2.268	6.512	0.979	0.927	1.025
MCH (pg)	16.94-37.24	0.970	0.970	0.428	1.476	0.953	0.936	0.973
MCHC (g/dL)	30.90-36.06	0.654	10.582	8.171	13.072	0.677	0.603	0.748
RDW (%)	11.32-27.34	0.911	0.411	-0.508	1.273	0.955	0.889	1.025
PLT (10^3/µL)	9.25-930.66	0.990	0.705	-3.01	3.875	0.983	0.964	1.002
MPV (fL)	9.27-14.46	0.825	-0.432	-1.329	0.505	1.055	0.967	1.138
NEUT (10^3/µL)	0.00-83.11	0.994	-0.042	-0.130	0.011	1.017	0.999	1.033
LYMP (10^3/µL)	0.01-72.19	0.947	0.011	-0.025	0.053	0.998	0.968	1.033
MONO (10^3/µL)	0.01-9.48	0.930	-0.006	-0.031	0.007	1.006	0.964	1.056
EOS (10^3/µL)	0.00-4.10	0.946	0.008	0.004	0.012	0.998	0.966	1.031
BASO (10^3/µL)	0.00-0.77	0.415	-0.006	-0.016	-0.001	0.758	0.593	0.996
NEUT (%)	0.9-98.20	0.961	0.158	-1.138	1.465	1.012	0.991	1.033
LYMP (%)	1.30-93.10	0.980	0.717	0.395	1.139	0.986	0.967	1.005
MONO (%)	0.10-45.80	0.877	-0.146	-0.581	0.255	1.005	0.947	1.061
EO (%)	0.00-34.10	0.855	0.087	0.032	0.100	1.016	1.000	1.046
BASO (%)	0.00-6.50	0.277	-0.076	-0.193	-0.020	0.764	0.628	0.967

The data indicated that the predefined acceptance criteria were met for all the 20 measurands and in all tested ranges.

Clinical Sensitivity

Please refer to the 510(k) Summary for K222148

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

Please refer to the 510(k) Summary for K222148.

Matrix Comparison

Vein to Capillary

Please refer to the 510(k) Summary for K222148.

Direct vs Indirect Capillary

Please refer to the 510(k) Summary for K222148.

807.92 (b)(3): Conclusions from Analytical and Performance Data

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