

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

**A. 510(k) Number:**

k092116

**B. Purpose for Submission:**

New device

**C. Manufacturer and Instrument Name:**

Medica Corporation

EasyCell Cell Locator

**D. Type of Test or Tests Performed:**

White blood cells (WBC) differential, red blood cell (RBC) characterization and platelet estimation

**E. System Descriptions:**

1. Device Description:

The EasyCell Cell Locator (EasyCell) automatically locates and presents images of blood cells on peripheral smears. The operator reviews the suggested classification of each white cell according to type and may manually change the suggested classification of any cell. The operator can characterize red cell morphology and estimate platelets based on observed images. The EasyCell is intended to be used by skilled operators, trained in the use of the device and in the identification of blood cells.

The major components of the EasyCell include two microscopes with 10X and 100X magnification, a 30-position slide carousel, a slide gripper and a positioning system, and pattern recognition software. Each of the two microscopes is fitted with a CCD camera to allow digital image capture.

2. Principles of Operation:

The EasyCell automatically scans the slide and captures images of white blood cells, red blood cells and platelets. The images are preclassified by the instrument's ASSIST function and are displayed on the screen by cell type. Cell images are grouped into eight categories: Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Nucleated Red Blood Cells (NRBC), Smudge cells and Other, which is intended to hold morphologically abnormal cells.

Preclassification is accomplished using a neural-network classifier. A trained technologist then reviews the suggested classification of the cells. For each cell the technologist can either accept the EasyCell recommended classification or manually change the suggested classification to another cell type from an expanded list that includes the more frequently encountered abnormal cell types. The trained technologist can also review and report red blood cell morphology and can review the numbers of platelets observed and report a platelet estimate. Results are saved on the dedicated computer and can be reviewed, exported to a laboratory information system, or printed. The EasyCell is network ready and can be integrated into a laboratory computer network.

3. Modes of Operation:

Fully Automated Scan and Image Acquisition

4. Specimen Identification:

Glass microscope slides are labeled with barcodes. Up to thirty oiled slides can be placed in a carousel.

5. Specimen Sampling and Handling:

EasyCell scans oiled peripheral blood smears on glass microscope slides.

6. Calibration:

Calibration of the system is a two-step operation consisting of target location (for positional calibration) and white balancing (for optical calibration). The built-in target is used for both functions, so there are no additional external calibrators.

The user performs the positional calibration by choosing “Target Locator” from the setup menu within the EasyCell software, and performs the optical calibration by choosing “Calibration” from the setup menu.

The “Target Locator” function is recommended for daily use, and helps the user set three critical stage locations within the EasyCell system: 10X Target Location, 100X Target Location and 10X Slide Focal Plane Location. “Calibration” function is recommended for weekly use, and it automatically adjusts and records the white balance settings for the target under both the 10x and 100x microscopes.

7. Quality Control:

One normal slide and one abnormal slide should be selected from the standard workflow and processed using the EasyCell locating 200 cells for Quality Control (QC) testing each day that slides are processed. The QC procedure controls for slide preparation (both smearing and staining) and EasyCell performance. If the QC procedure does not pass, the operator must resolve the problem and rerun the QC before processing samples.

8. Software:

FDA has reviewed applicant’s Hazard Analysis and Software Development processes for this line of product types:

Yes   X   or No           

**F. Regulatory Information:**

1. Regulation section:

21 CFR §864.5260, Automated Cell-Locating Device

2. Classification:

Class II

3. Product code:

JOY: Device, automated cell-locating

4. Panel:

Hematology (81)

**G. Intended Use:**

1. Indication(s) for Use:

The EasyCell 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.

2. Special Conditions for Use Statement(s):

Not applicable

**H. Substantial Equivalence Information:**

1. Predicate Device Name(s) and 510(k) numbers:  
CellaVision DM96 Automatic Hematology Analyzer, k033840
2. Comparison with Predicate Device:

<b>Similarities</b>		
Item	Device	Predicate
Intended Use	The EasyCell automatically locates and displays 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.	Automated cell locating device for cell-location, and identification, for in-vitro use. Verification of results by human operator.
Sample Type	Stained blood film glass slides of peripheral whole blood.	Same
Sample Preparation	Romanowsky stain	Same
Analysis Technique	<p>White blood cells: Cells are located/counted by moving according to the battlement pattern. 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 operator verifies the suggested classification by accepting or reclassifying.</p> <p>Red blood cells: The device presents an overview image. The examiners characterize red blood cell morphology from the image.</p> <p>Platelets: The device presents an overview image. The examiners manually count and estimate the platelet concentration from the overview image according to a standardized procedure.</p>	Same

**I. Special Control/Guidance Document Referenced (if applicable):**

Not available.

**J. Performance Characteristics:**

1. Analytical Performance:
  - a. *Accuracy:* A Method Comparison study was conducted to compare the EasyCell using Examiner Review to manual WBC differential microscopic

examination. A total of 304 specimens, including 155 specimens from normal (healthy) subjects and 149 from subjects with specific disease conditions, were collected and analyzed at three sites. Slides were prepared from each specimen. The slides were randomly selected, blinded and read by two technologists at each site. A total of 200 cells were counted for manual WBC differential and by EasyCell.

- i. WBC Differential: Results from Deming regression analyses on readings with EasyCell and manual WBC differential are as follows:

Cell Type	Correlation Coefficient (r)	Slope	Intercept
Neutrophil	0.99	1.00	0.39
Lymphocyte	0.98	1.00	0.88
Monocyte	0.93	0.85	0.59
Eosinophil	0.97	0.95	0.07

Clinical sensitivity and specificity of the EasyCell in identification of morphological and distributional abnormalities were determined based on the results of the manual WBC differential as either normal (i.e. containing no abnormal cells or having normal distributions of normal cells) or abnormal (i.e. containing morphologically abnormal cells or having abnormal distributions of normal cells).

	Morphological Abnormality	Distributional Abnormality	Overall
% agreement	82%	89%	84%
Sensitivity	84%	92%	91%
Specificity	82%	87%	72%

- ii. Platelet Estimate Accuracy: Platelet counts were estimated by each method as decreased (100,000 to 149,000 platelets), normal (150,000 to 400,000 platelets), or increased (401,000 to 499,000 platelets). A Cohen’s kappa statistic was calculated to demonstrate the agreement between the manual microscopy and EasyCell methods for each technologist. The data show a good agreement between platelet estimates using the manual microscopy and using EasyCell with a kappa score of 0.7 for each technologist.
- iii. RBC Morphology Accuracy: For each slide, the technologists classified the red blood cells according to morphology with the manual microscopy and EasyCell methods. The results showed >90% agreement between the two methods.

b. Precision/Reproducibility:

A precision/reproducibility study was performed at three different sites. Each site prepared 20 slides from a different normal patient sample and used one slide a day to perform a 200-cell differential count with both the manual WBC differential and the EasyCell for a total of 20 days. The data show that

precision of WBC differential with EasyCell is similar to that produced by the manual WBC differential at each study site.

- c. *Linearity:*  
Not applicable
- d. *Carryover:*  
Not applicable
- e. *Interfering Substances:*  
Not applicable

2. Other Supportive Instrument Performance Data Not Covered Above:

a. *Skip Rate*

A study was performed to determine the rate of cells that were skipped when moving from one field of view to the next. A total of 40 slides from 40 unique donors (20 normal, 20 abnormal) and a total of 11,151 WBC candidates were examined. A total of 74 cells were skipped, for a skip rate of 0.66%, which was considered and deemed acceptable in the hazard analysis.

b. *Reproducibility of Pre-Classification*

A total of 20 slides from 10 normal and 10 abnormal samples were run on three different EasyCell units for 5 consecutive days. Each slide was re-blinded and re-randomized each day for reading. Overall imprecision of pre-classification results from these repeated readings of the same 20 slides was estimated as follows:

	Normal Specimens (n=150 readings)		Abnormal Specimens (n=150 readings)	
	Mean (%)	SD	Mean (%)	SD
Neutrophil	63.0	4.7	47.0	4.2
Lymphocyte	23.8	4.2	19.5	2.9
Monocyte	6.1	1.9	13.0	2.7
Eosinophil	2.7	1.8	5.3	4.8
Basophil	1.8	1.6	4.4	2.8
Other (unclassified)	2.5	1.7	10.6	3.4
NRBC	1.9	1.6	9.4	4.5
Smudge	4.4	7.2	22.2	21.7

c. *Normal Reference Ranges*

	Manual WBC Differential	EasyCell
No. of samples	155	155
Neutrophils	42.8% - 78.5%	43.1% - 77.5%
Lymphocytes	14.8% - 43.8%	13.8% - 42.5%
Monocytes	3.0% - 13.8%	2.8% - 12.9%
Eosinophils	0.5% - 5.8%	0.6% - 5.3%
Basophils	0.0% - 2.0%	0.0% - 2.5%

d. *100 vs 200 Total Cell Count*

Slides from the clinical accuracy study were also counted by EasyCell using 100 cell counts. The 100 cell count results were compared to the 200 cell count by manual WBC differential.

Cell Type	Correlation Coefficient (r)	Slope	Intercept
Neutrophil	0.96	0.99	-0.15
Lymphocyte	0.95	1.00	0.73
Monocyte	0.83	0.83	0.72
Eosinophil	0.93	0.99	-0.01

As compared to the 200-cell count manual WBC differential, EasyCell with 100 cell counts showed similar clinical sensitivity and specificity as EasyCell with 100 cell counts in identifying morphological and distributional abnormalities based on the results of the manual WBC differential as either normal (i.e. containing no abnormal cells or having normal distributions of normal cells) or abnormal (i.e. containing morphologically abnormal cells or having abnormal distributions of normal cells).

	EasyCell - 200 Cell Counts	EasyCell - 100 Cell Counts
% agreement	84%	83%
Sensitivity	91%	90%
Specificity	72%	70%

**K. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**L. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.