

### 510(k) Summary

1. Device Name and Classification

Trade or Proprietary Name: EasyCell  
Common or Usual Name: Automated Cell-Locating Device  
Product Code: JOY  
Product Classification: Class 2  
Review Panel: Hematology  
Regulation Number: 21CFR864.5260

**MAY 12 2010**

2. Description of the Device

The 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.

3. Substantial Equivalency

The EasyCell is substantially equivalent to the CellaVision DM96 Automatic Hematology Analyzer.

#### Predicate Device Information

Manufacturer: CellaVision AB, Lund, Sweden  
Product: CellaVision DM96 Automatic Hematology Analyzer  
510(k) number: K033840

4. Intended 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.

Characteristic	Predicate Device	EasyCell	Equivalent
Intended use	Automated cell-locating device for cell-location, and identification, for in-vitro use. Verification of results by human operator.	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.	✓
Sample type	Stained blood film on glass slides of peripheral whole blood.	Stained blood film on glass slides of peripheral whole blood.	✓
Sample preparation	Romanowsky stain	Romanowsky stain	✓
Analysis Technique: White Blood Cells	Cells are located/counted by moving according to the battlement track 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	Cells are located/counted by moving according to the battlement track 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 reviews the suggested classification, and accepts or reclassifies the images.	✓
Red Blood Cells	The device presents an overview image. The reviewer characterizes red blood cell morphology from the image.	The device presents a series of images. The reviewer characterizes red blood cell morphology from the images.	✓
Platelets	The device presents an overview image. The reviewers manually count and estimate the platelet concentration from the overview image according to a standardized procedure.	The device presents a series of images. The reviewers manually count and estimate the platelet concentration from the images according to a procedure in the Operator's Manual.	✓

5. Performance Characteristics

Method Comparison

A Method Comparison was conducted to compare the EasyCell using Examiner Review (the Test Method) to the Reference Method. The Reference Method is a manual differential microscopic examination of the peripheral blood slides by a trained technologist. A total of 304 specimens were collected and analyzed at three sites. 155 specimens were from normal (healthy) subjects and 149 were from subjects with specific disease conditions (see Table 1 and Table 3). Slides were prepared from each specimen. The slides were randomly selected, blinded and read by two technologists at each site.

**Table 1**  
**Correlation between Reference Method and Test Method**

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	0.066

Sensitivity and Specificity

The number of normal and abnormal slides determined by each method was compared to determine the clinical sensitivity and specificity of the EasyCell.

**Table 2**

	Morphological	Distributional	Overall
Efficiency (% agreement)	82%	89%	84%
Sensitivity	84%	92%	91%
Specificity	82%	87%	72%

Platelet Estimate Accuracy

Platelet counts were estimated by each method as decreased, normal, or increased; and a corresponding value of 1, 2, or 3 was entered in the database. A Cohen's kappa statistic was calculated to demonstrate the agreement between the Test Method and the Reference Method for each technologist. The data show a good agreement between platelet estimates using the Reference Method and using the Test Method.

Red Blood Cell Morphology Accuracy

For each slide, the technologists classified the red blood cells according to morphology. This was done for both methods. The results showed >90% agreement between methods.

**Between Run Precision**

20 slides were made from one normal patient sample at each site. Each slide was labeled. Each day for 20 days a slide was chosen at random and a 200-cell differential count was made using both the Reference Method and the Test Method. The results show the Test Method has equivalent precision to the Reference Method.

**100 vs 200 Total Cell Count**

In order to confirm the equivalence of total cell counts of 100 and 200 cells, data from three sites were compared. 304 slides were evaluated using a total count of 100 cells.

The 100 cell results were compared to the 200 cell count Reference Method results. The data showed good correlation between the Reference method and the 100-cell counts.

**Table 3**  
**Correlation between Reference Method and Test Method by Cell Type**

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

**Table 4**  
**Comparison of Test Method to Reference Method Results (200 vs 100 cells)**

	Test method (200 cells)	Test Method (100 cells)
Efficiency (% agreement)	84%	83%
Sensitivity	91%	90%
Specificity	72%	70%



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
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Document Mail Center – WO66-0609  
Silver Spring, MD 20993-0002

Medica Corporation  
c/o Ms. Fran White  
Regulatory Consultant  
163 Cabot Street  
Beverly, MA 01915

**MAY 12 2010**

Re: k092116

Trade/Device Name: EasyCell Cell Locator  
Regulation Number: 21 CFR §864.5260  
Regulation Name: Automated Cell-Locating Device  
Regulatory Class: Class II  
Product Code: JOY  
Dated: March 24, 2010  
Received: April 28, 2010

Dear Ms. White:

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. 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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

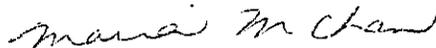
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notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Maria M. Chan, Ph.D  
Director  
Division of Immunology and Hematology Devices  
Office of *In Vitro* Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

### Indications for Use

#### Indications for Use

510(k) Number (if known): K092116

Device Name: EasyCell Cell Locator

Indications 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.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

*Marie M Chan*

Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K092116

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