510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

K080595

B. Purpose for Submission:

Expanded intended use

C. Manufacturer and Instrument Name:

CellaVision AB, CellaVision DM 96 with the body fluid application

D. Type of Test or Tests Performed:

White Blood Cells (differential), RBC characterization and Platelet estimation

E. System Descriptions:

1. Device Description:

   CellaVision DM96 consist as of a slide feeder unit, an optical unit consisting of a microscope and camera (referred to as a slide scanning unit), a computer system contains the acquisition and classification software CellaVision DM software.

   CellaVision DM96 with the body fluid application is substantially equivalent to the DM96 for peripheral blood regarding technology and functionality. The intended use of the body fluid application is substantially equivalent to the Romanowsky stain manual light microscopic method of cell classification.

   The body fluid application functionality:

   - Presents an image on a screen of every located cell or object
   - Organizes and suggests cell classification (reclassification) for the located blood cells
   - Makes it possible to identify, confirm or modify (reclassification) the suggested classification of the located cells

2. Principles of Operation:

   Twelve slides can be loaded into each magazine. The magazine used for the body fluid application is identified through the color and the barcode on it.

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The magazines are put onto a conveyer belt and are automatically transported to the slide scanning unit. The analysis process consists of an overview image processing and a cell-location step. The body fluid overview image displays the entire sample area. The overview image can be used to find cells of interest and for getting an overall impression of the sample. The overview image can either have one 10x zoom level or both 10x and 50x zoom levels. The cell-location step uses the optical unit and a camera taking images of the identified images and stores the images of the located cells and the results in a database, and displays the images in an organized manner.

3. Modes of Operation:

   The DM96 is an automated cell-locating device. The system also has Remote Review Station capability with network access to the main DM96 device.

4. Specimen Identification:

   Glass microscope slides are labeled with barcodes. Twelve slides fit into a barcoded labeled magazine.

5. Specimen Sampling and Handling:

   Body fluid is cytocentrifuged and stained outside the device on standard rectangular glass slides by standardized stained with Romanowsky stain.

6. Calibration:

   Not applicable.

7. Quality Control:

   The system performs self-tests during startup of the software, and at certain points during the operation of the system. Both hardware and software components are tested. The Cell location test is used to verify the slide preparation process and the system hardware. Running the test once or twice a day is a recommended interval at the high-load laboratory.

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, 21 CFR 864.5220

2. Classification:

   Class II

3 Product code:

   JOY, GKZ

4. Panel:

   Hematology (81)

G. Intended Use:

1. Indication(s) for Use:

   DM96 is an automated cell-locating device.

   The body fluid application is intended for differential count of white blood cells. The system automatically locates and presents images of cells on cytocentrifuged body fluid preparations. The operator identifies and verifies the suggested classification of each cell according to type.

   DM96 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

2. Special Conditions for Use Statement(s):

   Not applicable.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   CellaVision DM96, K033840
   Manual Light Microscope (Romanowsky stain process), Class I

2. Comparison with Predicate Device:

		Similarities	
Item	DM96 with Body Fluid Application	Manual light microscope process	DM96
Intended Use	Automated cell-locating device for identification of cytocentrifuged body fluids, for in-vitro diagnostic use. Verification of results by skilled human operator.	Manual method for cell-location and identification of blood smears and cytocentrifuged body fluids, for in-vitro diagnostic use. Verification of results by skilled human operator.	Automated cell-locating device for identification of cytocentrifuged body fluids, for in-vitro diagnostic use. Verification of results by skilled human operator.
Specimen type	Body fluids such as cerebrospinal and, serous fluid. Peripheral blood	Peripheral blood and body fluids.	Peripheral blood
Sample preparation	Body fluid samples are prepared by using a cytocentrifuged and stained with Romanowsky stain.	Romanowsky stained blood film on glass slides of peripheral blood. Body fluid samples are prepared using a cytocentrifuged and stained with Romanowsky stain.	Romanowsky stained blood film on glass slides of peripheral blood.
Analysis technique	White blood cells: Cells are located/counted by moving according to the battlement track pattern. Cells images are analyzed using standard mathematical methods. The cell images are pre-classified and the operator verifies the classification.	White blood cells: The examiners usually located/counted by moving according to the battlement track pattern on the smear and distinguish between classes of white blood cells.	White blood cells: Cells are located/counted by moving according to the battlement track pattern. Cells images are analyzed using standard mathematical methods. The cell images are pre-classified and the operator verifies the classification.
Overview image	The device presents an overview image. The image gives the operator possibilities to get an overview on parts of or the whole slide in different magnifications.	The operator scans the slide to get an overview on parts of or the whole slide in different magnifications.	The device presents an overview image. The image gives the operator possibilities to get an overview on parts of or the whole slide in different magnifications.

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

EP9-A2 *Method Comparison and Bias Estimation Using Patient Samples*, Approved Standard-Second Edition, NCCLS
EP5A *Evaluation of Precision Performance of Clinical Chemistry Device Approved Guideline*, NCCLS
H20-A *Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrument Methods, Approved Standard*, NCCLS
H56-A *Body Fluid Analysis for cellular composition; Approved guideline, CLSI*

J. Performance Characteristics*:*

1. <u>Analytical Performance</u>:

   a. *Accuracy*:

      A mixture of 156 samples (89 CSF and 69 BF) was identified according to EP9A-2 from two sites. All samples were initially analyzed on a cell counter or counted in a hemocytometer to get the leukocyte concentration. From each sample two cytocentrifuged smears were prepared. 200-cell differential counts were performed (400 cells/sample) with both methods and analyzed. The same examiners analyzed the same slides. The accuracy was tested through scatter-plots for each cell class.

      Samples included in the study.

Defined as in study	Type	number
CSF	CSF	89
Serous	Peritoneal fluid	24
Serous	Pleural fluid	46

      Results for all samples included are as follows:

Cell Class	Accuracy	95% CI Slope	n
Neutrophils	y= 1.0166x - 0.0030 r^2=0.9903	1.0006 - 1.0326	156
Lymphocytes	y= 1.9840x - 0.0011 r^2=0.9788	0.9609 - 1.0070	156
Macrophages	y= 0.9554x - 0.0113 r^2=0.9648	0.9264 - 0.9845	156
Eosinophils	y= 1.1352x - 0.0018 r^2=0.9737	1.1055 - 1.1649	156
Other cells	y= 1.0808x - 0.0019 r^2=0.9566	1.0442 - 1.1174	156

      Cells pre-classified as Basophils, Lymphoma cells, Atypical lymphocytes, Blasts and Tumor cells are automatically are forwarded to the cell class *Other*.

b. *Precision/Reproducibility*:

Short-term imprecision is equivalent for the test and reference method.

Short term imprecision results found on clinical evaluation on 156 samples

Cell Class	Test Method	Reference Method
	SD%	SD%
Neutrophils	3.4	3.6
Lymphocytes	0.8	1.0
Macrophages	6.0	6.1
Eosinophils	6.3	6.1
Other cells	2.2	1.6

c. *Linearity*:

Not applicable.

d. *Carryover*:

Not applicable

e. *Interfering Substances*:

Not applicable.

2. <u>Other Supportive Instrument Performance Data Not Covered Above:</u>

Not applicable.

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.