510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k102778

B. Purpose for Submission:
Modification of device for additional body fluid application

C. Manufacturer and Instrument Name:
CellaVision AB, CellaVision® DM 1200 with the body fluid application

D. Type of Test or Tests Performed:
White Blood Cells differential (peripheral blood smear), RBC characterization, Platelet estimation, White Blood Cells differential (cytocentrifuged body fluid smear).

E. System Descriptions:

1. Device Description:
   CellaVision® DM 1200 with the body fluid application is very similar to the predicate (CellaVision® DM96 with the body fluid application, k080595) in terms of technology, functionality, and intended use. The device automatically locates and presents images of nucleated cells on cytocentrifuged body fluid preparations. The system suggests a classification for each cell and the operator verifies the classification and has the opportunity to change the suggested classification of any cell. The system preclassifies to the following WBC classes: Unidentified, Neutrophils, Eosinophils, Lymphocytes, Macrophages (including Monocytes) and Other. Cells preclassified as Basophils, Lymphoma cells, Atypical Lymphocytes, Blasts and Tumor cells are automatically forwarded to the cell class Other. Unidentified is a class for cells and objects which the system has preclassified with a low confidence level.
2. Principles of Operation:
   Body fluid samples are prepared by using a cytocentrifuge and a staining unit. Twelve slides can be loaded into each magazine. The magazines are put into the system and the slides are then processed individually. 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 cells and transferring them to a computer system. The computer system preclassifies the 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 CellaVision® DM 1200 is an automated cell-locating device. Stained slides are loaded into a magazine with the capacity for 12 slides. The device fits one magazine.
4. Specimen Identification:
   The device requires barcode labeled slides for processing.
5. Specimen Sampling and Handling:

Glass slide with ground or clipped corners containing cytocentrifuged and stained body fluid is analyzed. The cytocetrifugation and staining occurs separately from the device.

6. Calibration:
   Not applicable
7. Quality Control:
   The cell location test is used to verify the slide preparation process and the system hardware. In addition, the device performs self-tests during startup of the software, and at certain points during the operation of the system. When the software starts, the system is checked before the operator can start analyses.
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
4. Panel:
   Hematology (81)

G. Intended Use:

1. Indication(s) for Use:
   DM1200 is an automated system intended for in-vitro diagnostic use.
   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.
   DM1200 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 with the body fluid application, k080595
2. Comparison with Predicate Device:

Similarities		
Item	DM1200	DM96 (Predicate)
Intended use	Automated cell-locating device for cell-location and identification of white blood cells in cytocentrifuged body fluid preparations, for in-vitro diagnostic use. Verification of results by skilled human operator.	Same

Similarities		
Item	DM1200	DM96 (Predicate)
Sample type/Sample preparation	Body fluid samples are prepared using a cytocentrifuge and stained with a Romanowsky stain.	Same
Analysis technique	Nucleated 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 preclassified by the system and the operator verifies the suggested classification by either accepting or reclassifying.	Same
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.	Same

Differences		
Item	DM1200	DM96 (Predicate)
Slide handling/ Loading capacity	Slides are loaded into a magazine with the capacity of 12 slides. Device fits one magazine.	Slides are loaded into magazines with the capacity of 12 slides each. Device fits eight magazines.
Throughput estimate	3 to 15 slides per hour for differential	7 to 25 slides per hour for differential

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

EP05-A2, *Evaluation of Precision Performance of Quantitative Measurement Methods. Approved Guideline – Second Edition.* CLSI

EP09-A2, *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline, Second Edition.* CLSI

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy:

A method comparison of CellaVision® DM 1200 with the body fluid application (test method) and Cellavision® DM96 with the body fluid application (predicate method) was performed. A 200-cell differential leukocyte count was obtained on duplicate slides. The study occurred at two separate clinical sites. The acceptance criteria are as follows: Slope between 0.9 – 1.1 within 95% confidence interval and an intercept between -0.1 - +0.1 within the 95% confidence interval.

Total samples included in the study.

Type	Number of samples
CSF	62
Serous fluid	151
Synovial fluid	47
Total	**260**

Accuracy results. All samples included (pooled data).

Cell class	Accuracy	95% CI Slope	95% CI Intercept	Number of samples
Neutrophils	y = 0.9969x + 0.0050 R^2= 0.9932	0.9868–1.0070	0.0004–0.0096	260
Lymphocytes	y = 0.9815x + 0.0016 R^2 = 0.9829	0.9656–0.9973	-0.0049–0.0081	260
Eosinophils	y = 1.1048x - 0.0002 R^2 = 0.9629	1.0782–1.1314	-0.0007–0.0003	260
Macrophages	y = 1.0067x - 0.0050 R^2 = 0.9823	0.9901–1.0232	-0.0125–0.0024	260
Other cells	y = 0.9534 + 0.0032 R^2 = 0.9273	0.9207–0.9861	-0.0002–0.0065	260

b. Precision

Repeatability:

Two samples were prepared in duplicate and labeled sample A and sample B. The evaluation consisted of a 200-cell differential count performed on cytocentrifuged body fluid preparations. The differential count was repeated twenty times (n = 20) using two CellaVision® DM 1200 instruments. Results of the study including acceptance criteria are displayed in the following tables:

Precision results sample A

Cell Class	Mean %	S_r % within-run	CV % within-run	S_T % within-device	CV % within-device	Acceptance Criteria
Neutrophils	3.8	1.6	N/A	1.5	N/A	≤ 3% SD
Lymphocytes	29.0	2.9	10.2	3.4	11.8	≤ 20% CV
Macrophages	63.0	2.6	4.2	3.1	3.9	≤ 8% CV
Other Cells	1.0	0.9	N/A	0.8	N/A	≤ 3% SD
Neutrophils	6.9	1.5	N/A	1.4	N/A	≤ 3% SD
Lymphocytes	30.1	4.2	13.9	3.9	12.9	≤ 20% CV
Macrophages	59.0	3.5	5.9	3.5	6.0	≤ 20% CV
Other Cells	1.0	1.0	N/A	0.9	N/A	≤ 3% SD

Precision results sample B

Cell Class	Mean %	S_r % within-run	CV % within-run	S_T % within-device	CV % within-device	Acceptance Criteria
Neutrophils	4.2	1.2	N/A	1.1	N/A	≤ 3% SD
Lymphocytes	71.2	2.6	3.7	2.2	3.1	≤ 8% CV
Macrophages	18.6	1.7	9.3	1.7	9.0	≤ 20% CV
Other Cells	2.2	0.8	N/A	0.7	N/A	≤ 3% SD
Neutrophils	3.3	1.6	N/A	1.2	N/A	≤ 3% SD
Lymphocytes	72.4	1.9	2.6	1.6	2.2	≤ 8% CV
Macrophages	20.2	1.7	8.7	1.4	7.0	≤ 20% CV
Other Cells	1.8	0.9	N/A	0.7	N/A	≤ 3% SD

Reproducibility

A reproducibility study was conducted at three sites using three CellaVision® DM 1200 instruments with each site processing the same twelve samples in duplicate, for 20 operating days (n = 120 per sample). All results of the study demonstrate that the precision of the CellaVision® DM 1200 between different devices, sites, operators, and days is within the acceptance criteria listed in the following table:

Precision acceptance criteria (reproducibility)

Differential value	Acceptance criteria
0-10 %	≤ 3% SD
11-60 %	≤ 20% CV
61-100 %	≤ 8% CV

c. *Linearity*:
Not applicable

d. *Carryover*:
Not applicable

e. *Interfering Substances*:
Not applicable

2. Other Supportive Instrument Performance Data Not Covered Above: none

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.