

1 510(k) Summary

Submitter: CellaVision AB
 Ideon Science Park
 SE-223 70 Lund
 Sweden
 Phone: +46 46 286 44 00
 Fax: +46 46 286 44 70

SEP 16 2011

Contact Information: C. G. Bundy Associates, Inc.
 435 Rice Creek Terrace NE
 Fridley, MN 55432
 USA
 Phone: 763-574-1976
 Fax: 763-571-2437

Submission Date: September 20, 2010

Device Name: Proprietary name: CellaVision® DM1200 with the body fluid application
 Common/Classification name: Automated cell-locating device

Classification Regulation: 21 CFR 864.5220 and 21 CFR 864.5260 Class II medical devices.

Equivalent Device Identification: CellaVision AB believes that CellaVision DM1200 with the body fluid application is substantially equivalent to the legally marketed CellaVision DM96 with the body fluid application (K080595).

Device Description: CellaVision DM1200 with the body fluid application 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.

Intended 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.

Table 3.1: Comparative features of CellaVision DM1200 with the body fluid application and the predicate device

Characteristic	DM96 with the body fluid application (predicate device)	DM1200 with the body fluid application	Equivalent
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.	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.	✓
Specimen type	Body fluids.	Body fluids.	✓
Sample preparation	Body fluid samples are prepared using a cytocentrifuge and stained with Romanowsky stain.	Body fluid samples are prepared using a cytocentrifuge and stained with Romanowsky stain.	✓
Analysis technique	<i>White blood cells:</i> 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.	<i>White blood cells:</i> 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.	✓
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 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.	✓

Performance characteristics:

A method comparison was conducted to compare CellaVision DM1200 with the body fluid application (Test Method) to CellaVision DM96 with the body fluid application (Reference Method).

Body fluid samples were collected 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 preparations were made. A 200-cell differential count was performed for each slide (400 cells/sample) with both the test method and the reference method. The results were then verified by skilled human operators. The comparison was based on the approved guideline, CLSI document EP9-A2.

Accuracy:

The accuracy was tested through scatter plots for each cell class.

Table 3.2: Samples included in the study.

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

Accuracy results for all samples included were as follows:

Table 3.3: 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

Precision/Reproducibility:

The table below shows the short-term imprecision results found for all 260 samples included in the clinical evaluation. The short-term imprecision was found to be equivalent for the test method and the reference method.

Table 3.4: Short-term imprecision (pooled data).

	Test Method		Reference Method	
	Mean % *	SD %	Mean % *	SD %
Neutrophils	32.0	3.2	31.6	3.4
Lymphocytes	30.1	5.6	30.5	5.7
Eosinophils	0.6	0.7	0.5	0.6
Macrophages	35.3	5.8	35.5	6.2
Other cells	2.1	1.7	1.9	2.5

$$* \text{Mean}\% = \frac{\sum_{i=1}^N x_{mean, \%}}{N} \text{ (mean of all results per cell type).}$$

Conclusion:

The body fluid application is a modification of the intended use of CellaVision DM1200 Automated Hematology Analyzer, cleared by FDA in 2009 (K092868). The intended use has been modified to also include presentation of white blood cells on cytocentrifuged body fluid preparations.

Based on extensive performance testing, including comparison to the predicate device, it is the conclusion of CellaVision AB that CellaVision DM1200 with the body fluid application is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns regarding safety and effectiveness.



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

CellaVision AB
c/o Ms. Constance G. Bundy
C. G. Bundy Associates, Inc.
435 Rice Creek Terrace NE
Fridley, MN 55432

SEP 16 2011

Re: k102778

Trade/Device Name: CellaVision[®] DM 1200 with body fluid application
Regulation Number: 21 CFR 864.5260
Regulation Name: Automated cell-locating device
Regulatory Class: Class II
Product Code: JOY
Dated: September 7, 2011
Received: September 9, 2011

Dear Ms. Bundy,

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

Page 2 – Ms. Constance G. Bundy

will allow you to begin marketing your device as described in your Section 510(k) premarket 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,

For 
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

1 Indications for Use Statement

510(k) Number (if known): k102778

Device Name: CellaVision® DM1200 with the body fluid application

Indications 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.

Prescription Use X OR Over the Counter Use _____
(Part 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Deena Philip
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K k102778