K080595

2 510(k) Summary

DEC 0 5 2008

Submitter: CellaVision AB
Ideon Science Park
SE-223 70 Lund
Sweden

Contact Information: C. G. Bundy Associates, Inc.
6470 Riverview Terrace
Fridley, MN 55432

Submission Date: February 27, 2008

Device Name and Classification: CellaVision DM96 with the body fluid application

21 CFR 864.5220 and 21 CFR 864.5260 Class II medical devices.

Equivalent Device Identification: CellaVision AB believes that DM96 with the additional body fluid application is substantially equivalent to the DM96 for peripheral blood regarding technology and function. The additional intended use of body fluid is substantially equivalent to the Romanowsky stain manual light microscopic process for cell classification (21CFR 864.3600 Class I exempted from pre-market notification procedure)

Device Description: The CellaVision DM96 with the body fluid application is a laboratory instrument used to perform differential analysis by locating, digitally storing and displaying cells in human body fluid preparations.

The CellaVision DM96 with the body fluid application is a new intended use that follows the same process as the currently cleared DM96 with white blood cell differential, RBC characterization and platelet estimation (K033840).

Intended 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

Comparison Table:

Comparative features of DM96 with Body Fluid application compared with the predicate device:

Characteristic	DM96 with Body Fluid Application	Manual light microscopic process	DM 96
Intended use	Automated cell-locating device for cell-location and 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 cell-location and identification of blood smears, for in-vitro diagnostic use. Verification of results by skilled human operator.
Specimen type	Body fluids such as cerebrospinal fluid, serous fluid, bronchoalveolar lavage, and related fluids.	Peripheral blood and body fluids such as cerebrospinal fluid, serous fluid, bronchoalveolar lavage, and related fluids.	Peripheral blood.
Sample preparation	Body fluid samples are prepared by using a cytocentrifuge and stained with Romanowsky stain.	Romanowsky stained blood film on glass slides of peripheral blood. Body fluid samples are prepared by using a cytocentrifuge 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. Cell images are analyzed using standard mathematical methods, including	*White blood cells:* The examiners usually locate/count white blood cells by moving according to the battlement track pattern on the smear and distinguish between classes of	*White blood cells:* Cells are located/counted by moving according to the battlement track pattern. Cell images are analyzed using standard mathematical methods, including

Characteristic	DM96 with Body Fluid Application	Manual light microscopic process	DM 96
	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.	white blood cells.	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.
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 of a part of the slide. The image gives the operator possibilities to get an overview of the part in different magnifications.

Summary of Testing:
The CellaVision DM96 was cleared by the FDA in 2004. The intended use has been modified to include presentation of white blood cells on cytocentrifuged body fluid preparations.

Tests on cytocentrifuged body fluid preparations including specimen types such as cerebrospinal fluid, serous fluid and related fluids were conducted and successfully completed.
Tests were also conducted to validate performance including accuracy, precision and cell-location.

Conclusion:
Based on extensive performance testing including comparison to the predicate devices, it is the conclusion of CellaVision AB that DM96 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 about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

CELLAVISION AB
c/o Bundy Associates, Inc.
6740 Riverview Terrace
Minneapolis, Minnesota 55432
ATTN: Constance G. Bundy

DEC 0 5 2008

Re: k080595
Trade/Device Name: CELLAVISION DM96 with the Body Fluid Application
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ, JOY
Dated: November 17, 2008
Received: November 21, 2008

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.

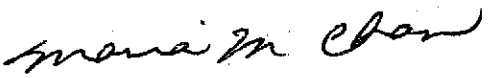
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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); 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 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 Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Maria M. Chan, Ph.D.
Acting Division 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

510(k) Number (if known): K080595

Device Name: CellaVision DM96 with the body fluid application

Indications For Use:

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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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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