

Section 2. SUMMARY AND CERTIFICATION

2.1. 510 (k) Summary

2.1.1. Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the 510(k) summary for DM96.

SUBMITTER'S NAME: CellaVision AB
ADDRESS: Ideon Research Park, SE-223 70 Lund, Sweden
CONTACT PERSON: Constance G. Bundy
TELEPHONE NUMBER: 763-574-1976
FAX NUMBER: 763-571-2437
DATE OF SUBMISSION: December 9, 2003

1. Identification of device

Proprietary Name: CellaVision DM96 Automatic Hematology Analyzer

Common Name: DM96

Classification Status: Class II per regulations 21CFR 864.5260

Product Codes: JOY

2. Equivalent devices

CellaVision AB believes DM96 is substantially equivalent to the Romanowsky stain manual light microscopic process for cell classification (21CFR 864.3600 Class I exempted from premarket notification procedure) and DiffMaster Octavia™ Hematology Analyzer, 510(k) number K003301, CellaVision AB.

3. Description of the device

DM96 is an automated cell-locating device for differential count of white blood cells, characterization of red blood cell morphology and platelet estimation. DM96 consists of a slide-scanning unit (a slide feeder, a microscope and a camera) and a computer system containing the acquisition and classification software "CellaVision Blood Differential software".

4. Intended use

DM96 is an automated cell-locating device.

DM96 automatically locates and presents images of blood cells on peripheral blood smears. 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.

5. Technological characteristics, comparison to predicate device

Like the predicate device, DM96 locates white blood cells, stores digital images of the cells and displays the images in an organized manner and suggests a cell class for each cell to aid operators in performing the differential count procedure. A competent operator is required to confirm or modify the suggested classification of each cell. It is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells. Like the predicate device, DM96 presents an overview image from which it is possible to characterize red blood cells regarding size, shape and color. In addition, the DM96 presents an overview image and facilitates platelet estimation.

Brief discussion of non-clinical factors supporting a determination of substantial equivalence:

The method requires a competent human examiner to review the microscopic images of the cells as does the predicate method and device. See substantial equivalence comparisons below.

Brief discussion of clinical tests supporting a determination of substantial equivalence:

A clinical evaluation has been performed to confirm equivalence with the predicate method DiffMaster Octavia™ for differentiation of white blood cells. The study has been performed according to a predefined protocol based upon the approved standard, NCCLS, vol. 23, no 1, document H-20A, March 1992: Reference Leukocyte Differential Count (proportional) and Evaluation of Instrumental Method. Complementary tests have been performed to confirm cell-location, precision and overview image quality.

Conclusions drawn from clinical tests:

The following information was obtained from the clinical tests:

- accuracy for cell-location
- accuracy for the verified classification for each cell class
- precision for the verified classification for each cell class
- clinical sensitivity and specificity

The results show that the DM96 is equivalent in accuracy, precision and clinical sensitivity and specificity and fulfilled the pre-defined requirements for overview image quality.

Comparative features of DM96 compared with the predicate devices:

Characteristic	Manual light microscopic process	DiffMaster Octavia™	DM 96
Intended use	Manual method for cell-location and identification, for in-vitro use. Verification of results by human operator.	Automated cell-locating device for cell-location, and identification, for in-vitro use. Verification of results by human operator.	Automated cell-locating device for cell-location, and identification, for in-vitro use. Verification of results by human operator.
Sample type	Stained blood film on glass slides of peripheral whole blood.	Stained blood film on glass slides of peripheral whole blood.	Stained blood film on glass slides of peripheral whole blood.

Characteristic	Manual light microscopic process	DiffMaster Octavia™	DM 96
Sample preparation	Romanowsky stain	Romanowsky stain	Romanowsky stain
Analysis technique	<p>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.</p> <p>Red blood cells: The examiners characterize red blood cell morphology from an overview.</p> <p>Platelets: The examiners manually count and estimate the platelet concentration from an overview according to a standardized procedure (21 CFR 864.6160 Manual blood cell counting device, Class I).</p>	<p>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.</p> <p>Red blood cells: The device presents an overview image. The examiners characterize red blood cell morphology from the image.</p>	<p>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.</p> <p>Red blood cells: The device presents an overview image. The examiners characterize red blood cell morphology from the image.</p> <p>Platelets: The device presents an overview image. The examiners manually count and estimate the platelet concentration from the overview image according to a standardized procedure.</p>

6. Discussion of Performance Testing.

An extensive collection of tests has been conducted and successfully completed, including tests to ensure safety, effectiveness, and compliance with product requirements.

The following tests were conducted and successfully completed:

a) Evaluation of:

- Performance (accuracy and precision, clinical sensitivity, specificity, cell-location)
- Safety

b) Inspections to verify that all design features are as intended and that all authorized design changes have been accomplished and recorded.

c) Validation of the system (including efficacy of user interface)

7. Conclusion

Based on extensive performance testing and a comparison to the predicate device, it is the conclusion of CellaVision AB that DM96 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

FEB 10 2004

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

CellaVision AB
c/o Ms. Constance G. Bundy
C. G. Bundy Associates, Inc.
6740 Riverview Terrace
Minneapolis, MN 55432

Re: k033840
Trade/Device Name: CellaVision DM96
Regulation Number: 21 CFR 864.5260
Regulation Name: Automated cell-locating device
Regulatory Class: Class II
Product Code: JOY; GKZ
Dated: December 9, 2003
Received: December 10, 2003

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).

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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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

Steven Gutman, M.D.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

1.2. Indications for Use

510(k) Number K033840

Device Name: CellaVision DM96

Indications for Use:

DM96 is an automated cell-locating device.

DM96 automatically locates and presents images of blood cells on peripheral blood smears. 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.

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_____ Concurrence of CDRH, Office of Device Evaluation (ODE) _____

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

Maria Chan for Josephina Baptista
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K033840