K092868

2 510(k) Summary

510(k) owner: CellaVision AB
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NOV 20 2009

Contact Information: C. G. Bundy Associates, Inc.
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Date of summary: September 14, 2009

Device Name:

- Proprietary Name: CellaVision® DM1200 Automated Hematology Analyzer
- Common/Classification Name: Automated Cell-locating device

Classification Regulation: 21 CFR 864.5260 Class II medical device

Product Code: JOY; GKZ

Predicate Device Identification: CellaVision AB believes that DM1200 is substantially equivalent to the legally marketed (unmodified) device DM96 (K033840) regarding technology and function.

Device Description: DM1200 is an automated cell-locating device for differential count of white blood cells, characterization of red blood cell morphology and platelet estimation. DM1200 consists of a slide scanning unit (a robot gripper, a microscope and a camera) and a computer system containing the acquisition and classification software "CellaVision® DM software".

Intended Use: DM1200 is an automated cell-locating device.

DM1200 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.

DM1200 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

Technological characteristics, comparison to predicate device
Like the predicate device, DM1200 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, DM1200 presents an overview image from which it is possible to characterize red blood cells regarding size, shape and color.

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.

Brief discussion of clinical tests supporting a determination of substantial equivalence:
A clinical evaluation has been performed to confirm equivalence with the predicate device DM96 for differentiation of white blood cells. The study has been performed according to a predefined protocol based upon the approved standard CLSI, H20-A2, *Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods*; 2nd Ed. and the approved guideline CLSI, EP05-A2, *Evaluation of Precision Performance of Quantative Measurement Methods,* 2nd Ed.. Complementary tests have been performed to confirm cell-location.

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 fulfilled the pre-defined requirements.

Conclusion:
Based on the performance testing where DM1200 was compared to the predicate devices, it is the conclusion of CellaVision AB that DM1200 is substantially equivalent to devices already on the market (cleared by the 510(k) process).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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

NOV 20 2009

Re: k092868
Trade/Device Name: CellaVision® DM1200 Automated Hematology Analyzer
Regulation Number: 21 CFR §864.5260
Regulation Name: Automated cell-locating device
Regulatory Class: Class II
Product Code: JOY, GKZ
Dated: November 09, 2009
Received: November 13, 2009

Dear Constance G. 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 (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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems

(QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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 Indication for use statement

510(k) Number (if known): K092868

Device Name: CellaVision® DM1200 Automated Hematology Analyzer

Indications for Use:

DM1200 is an automated cell-locating device.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Maria M Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K092868