K003301

MAR 1 5 2001

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

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

SUBMITTER'S NAME:	CellaVision AB
ADDRESS:	Ideon Research Park, 223 70 Lund, Sweden
CONTACT PERSON:	Constance G. Bundy
TELEPHONE NUMBER:	612-574-1976
FAX NUMBER:	612-571-2437
DATE OF SUBMISSION:	October 19, 2000

1. **Identification of device**
   Proprietary Name: DiffMaster Octavia™ Automatic Hematology Analyzer
   Common Name: DiffMaster Octavia™
   Classification Status: Class II per regulations 864-5260
   Product Codes: JOY

2. **Equivalent devices**
   CellaVision AB believes the DiffMaster Octavia™is substantially equivalent to the Romanowski (MGG)-Stain manual light microscopic process for cell classification and the IMI MICRO21 with WBC Diff (White blood cell Differential, 510(k) number K925670/A).

3. **Description of the Device**
   The DiffMaster Octavia™ is an automated cell locating device for differential count of white blood cells and characterization of red morphology. It is based on a CellaVision AB developed software system Cytologica. DiffMaster Octavia™consists of a commercially available positioning system for the slides, a commercially available microscope, a commercially available camera and the software system.

4. Intended use

The DiffMaster Octavia™ is an automated cell locating device.

DiffMaster Octavia automatically locates and presents images of blood cells on peripheral blood specimens. The operator identifies and verifies the suggested classification of each cell according to type.

DiffMaster Octavia is intended to be used by skilled operators, trained in the use of the instrument and in recognition of leukocyte classes.

5. Technological characteristics, comparison to predicate device

Like the predicate device, the DiffMaster Octavia™ instrument locates WBCs, stores digital images of the cells and displays the images in an organized manner and suggests a cell class for each cell to aid technologists in performing the WBC differential procedure. A competent technologist 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 instrument and in recognition of leukocyte classes.

Brief Discussion of Non clinical factors supporting a determination of substantial equivalence:
The method involves a competent human observer to examine the microscopic images of the cells as does the predicate method and device. See attached substantial equivalence comparisons.

Brief discussion of clinical tests supporting a determination of substantial equivalence:
Two clinical trials have been performed to confirm equivalence with the predicate method Romanowski (MGG)-Stain manual light microscopic process for cell classification. The studies have been performed according to the approved standard, NCCLS, vol. 23, no 1, document H-20A, March 1992: Reference Leukocyte Differential Count (proportional) and Evaluation of Instrumental Method. Complementary nonclinical tests have been performed to confirm cell location and display of found cells.

Conclusions drawn from clinical tests:
The following information was obtained from the clinical tests comparing the DiffMaster Octavia™ cell classification results to the manual reference method results:

- the accuracy of the suggested classification for each cell type (DiffMaster Octavia™ results compared to the light microscope manual diff count results)
- the precision for location and display of the cells found
- the precision of the instrument (reproducibility)
- the sensitivity and the specificity of the instrument (false positive and false negatives found)

Results equal to the reference method was provided by use of the DiffMaster Octavia™ instrument.

Comparative features of the DiffMaster Octavia compared with the predicate device and method

Characteristic	IMI Micro21	Manual light microscopic process	DiffMaster Octavia™
Intended use	Automated cell location device for cell location and identification, for in-vitro use. Verification of results by human observer	Manual method for cell location and identification, for in-vitro use. Verification of results by human observer	Automated cell locating device for cell location, and identification, for in-vitro use. Verification of results by human observer
Sample type	Bloodfilm on glass slides of peripheral whole blood, stained	Bloodfilm on glass slides of peripheral whole blood, stained	Bloodfilm on glass slides of peripheral whole blood, stained
Sample preparation	Wright, Wright Giemsa, May Grünwald stain	May Grünwald Giemsa stain (MGG)	May Grünwald Giemsa stain (MGG)
Analysis technique	Cells are located using the NCCLS scanning procedure. Cell images are analyzed using standard mathematical methods, including deterministic artificial neural networks (ANN's) trained to distinguish between classes of white blood cells.		Cells are located using the NCCLS scanning procedure. Cell images are analyzed using standard mathematical methods, including deterministic artificial neural networks (ANN's) trained to distinguish between classes of white blood cells

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 as prototype tests 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 the DiffMaster Octavia™ is substantially equivalent to devices already on the marked (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

MAR 1 5 2001

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

Re: K003301
Trade Name: DiffMaster Octavia™ Automatic Hematology Analyzer
Regulatory Class: II
Product Code: JOY
Dated: February 16, 2001
Received: February 20, 2001

Dear Ms. Bundy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(k) Number K003301

Device Name: DiffMaster Octavia™

Indications for Use:

The DiffMaster Octavia™ is an automated cell locating device.

DiffMaster Octavia automatically locates and presents images of blood cells on peripheral blood specimens. The operator identifies and verifies the suggested classification of each cell according to type.

DiffMaster Octavia is intended to be used by skilled operators, trained in the use of the instrument and in recognition of leukocyte classes.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003301

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over the Counter Use_____
(Per 21 CFR 801.109)