October 16, 2020

CellaVision AB
% Jinjie Hu
President and Principle Consultant
Axteria BioMed Consulting Inc.
8040 Cobble Creek Circle
Potomac, Maryland 20854

Re: K200595
Trade/Device Name: CellaVision DC-1, CellaVision DC-1 PPA
Regulation Number: 21 CFR 864.5260
Regulation Name: Automated Cell-Locating Device
Regulatory Class: Class II
Product Code: JOY
Dated: September 19, 2019
Received: March 6, 2020

Dear Jinjie Hu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Takeesha Taylor-Bell
Chief
Division of Immunology
and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200595

Device Name

CellaVision® DC-1

Indications for Use *(Describe)*

Intended use of CellaVision® DC-1
CellaVision® DC-1 is an automated cell-locating device intended for in-vitro diagnostic use in clinical laboratories.
CellaVision® DC-1 is intended to be used by operators, trained in the use of the device.

Intended use of the Peripheral Blood Application
The Peripheral Blood Application is intended for differential count of white blood cells (WBC), characterization of red blood cell (RBC) morphology and platelet estimation. The CellaVision® DC-1 with the Peripheral Blood Application automatically locates blood cells on peripheral blood (PB) smears. The application presents images of the blood cells for review. A skilled operator trained in recognition of blood cells, identifies and verifies the suggested classification of each cell according to type.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5 510(k) Summary

5.1 General Information

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Date Prepared: March 06, 2020

Purpose of Submission: To obtain a substantial equivalence for the CellaVision® DC-1 device.

5.2 Measurand

White Blood Cells (WBC), Red Blood Cells (RBC) and Platelets (PLT).

5.3 Device

Proprietary Name of the device:	CellaVision® DC-1and CellaVision® DC-1 PPA
Classification name:	Automated cell-locating device
Regulation number:	21 CFR 864.5260
Classification Name and Reference:	Class II
Device product Code:	JOY
Panel:	Hematology

5.4 Intended use/Indication for use

CellaVision® DC-1 is an automated cell-locating device intended for in-vitro diagnostic use in clinical laboratories.
CellaVision® DC-1 is intended to be used by operators, trained in the use of the device.

5.5 Intended use of the Peripheral Blood Application

The CellaVision Peripheral Blood Application is intended for differential count of white blood cells (WBC), characterization of red blood cell (RBC) morphology and platelet estimation. The CellaVision® DC-1 with the Peripheral Blood Application automatically locates blood cells on peripheral blood (PB) smears. The application presents images of the blood cells for review. A skilled operator trained in recognition of blood cells, identifies and verifies the suggested classification of each cell according to type.

5.6 Device Description

The CellaVision® DC-1 is an automated cell-locating device intended for in-vitro diagnostic use. CellaVision® DC-1 automatically locates and presents images of blood cells found on peripheral blood smears. The operator identifies and verifies the suggested classification of each cell according to type. CellaVision® DC-1 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells

The CellaVision® DC-1 consists of a built-in PC with a Solid-State Disc (SSD) containing CellaVision DM Software (CDMS), a high-power magnification microscope with a LED illumination, an XY stage, a proprietary camera with firmware, built-in motor- and illumination LED controller, a casing and an external power supply. It is capable of handling one slide at a time.

The CellaVision® DC-1 can preclassify WBCs and precharacterize RBCs by use of artificial intelligence. For the larger system (DM1200), preclassification and precharacterization are performed using the Artificial Neural Network (ANN). For the CellaVision® DC-1 Convolutional Neural Networks (CNN) are used instead of ANN. The results from the clinical performance evaluations shows that the two systems (CellaVision® DC-1, tested device and CellaVision® DM1200, predicate device) have similar performance when preclassifying WBCs and precharacterizing RBCs using to the two different network types.

The CellaVision® DC-1 is for prescription use only.

5.6.1 Physical Properties of the CellaVision® DC-1

Weight: 11kg (24lb)
Width: 280mm (11.0 inches)
Depth: 390mm (15.4 inches)
Height: 370 mm (14.6 inches)

5.6.2 Components of the CellaVision® DC-1

Computer module (integrated)
Motorized microscope
Digital color camera
Control unit
Casing
Database

5.6.3 Consumables Required to produce blood smears to be used on CellaVision® DC-1

Romanowsky stain (May Grünwald Giemsa (MGG), Wright Giemsa (WG) or Wright (W) staining)
Slides

EDTA sample tube (K_2EDTA or K_3EDTA)
Automatic slide maker-stainer, or stain slides manually

5.6.4 Specimen identification

Peripheral blood samples typically flagged by a cell-counter indicating an abnormal morphology.

5.6.5 Anticoagulant

All samples used in the analytical and clinical studies were collected using K_3EDTA as the anticoagulant. The protocols used in these studies state that both K_2EDTA and K_3EDTA are acceptable to use.
Studies [1, 2] have confirmed the equivalence between the two anticoagulants and that any difference between the two anticoagulants are minimal and unlikely to be of any clinical significance. Furthermore, the recognized CLSI standard [3] no longer defines K_2EDTA and K_3EDTA as separate EDTA options (recognition number 7-221).
It is concluded that, based on available scientific literature that any differences between results obtained with blood collected in K_3EDTA tubes vs blood collected in K_2EDTA are minimal and unlikely to be of any clinical significance. [1]

5.6.6 Calibration

CellaVision recommends that calibration is performed once a year by a service engineer.

5.6.7 Quality control

5.6.7.1 Self-Test

The CellaVision® DC-1 analyzer performs self-tests during startup of the software, and at certain points during the operation of the analyzer. When the software starts, the analyzer is checked before the user can start analyzing. During this phase, both the hardware and the software components are tested for anomalies, as well as various requirements for the operation of the analyzer. If the LIS communication is enabled, the program will also check the connection to the LIS.
The communication with, and response of the hardware, is tested continuously during the operation of the analyzer, and a message will inform the user if an error occurs during slide processing or other operations on the analyzer.

5.6.7.2 Cell Location Test

A cell location test shall be run at least once a day and after any changes in the staining procedure or the staining solutions for quality control. Cell location slides are prepared and processed by the customer from a freshly stained slide from a blood sample with a WBC

[1] List of references:
[1] Lab Hematol. 1998; 4:17-20. "Performance of K2EDTA- vs K3EDTA-collected blood specimens on various hematology analyzers"
[2] Lab Hematol. 2003; 9 (1):10-4. "Comparison of glass K3EDTA versus plastic K2EDTA blood-drawing tubes for complete blood counts, reticulocyte counts, and white blood cell differentials." Van Cott EM et al.
[3] CLSI GP39-A6 (former CLSI H01-A6) "Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard – Sixth Edition."

count within the normal range. The cell location test verifies that the quality of the slide preparation process is good enough to allow the analyzer to locate the cells needed for the analysis. It also verifies the analyzer's ability to locate cells. More details on the cell location test can be found in the CellaVision® DC-1 Instructions for Use.

5.6.8 Principle of operation

From a peripheral blood sample, typically flagged by a cell-counter indicating an abnormal morphology, a thin blood film is wedged on a glass slide (a blood smear). The blood smear is then stained with Romanowsky stain. The system uses stained microscope slides from EDTA-anticoagulated whole blood.

The operator enters the order ID for the slide, either manually or using an optional barcode reader. If a Laboratory Information System (LIS) is used, the device automatically fetches order data for the sample from the LIS.

The operator places the slide in the loading tray of the device and closes the input hatch. The device automatically moves the slide under the microscope.

Starting at 33 mm from the edge of the slide, the device looks for a monolayer in the smear. Once a monolayer is found, the device scans the monolayer in a battlement pattern. While doing this, the device locates any WBCs and stores high quality images of each located WBC. The device also locates and stores an image of a part of the RBC monolayer. When enough WBCs and the image of the RBC monolayer have been captured, the analyzer moves the slide back to the loading tray.

The device software pre-classifies each located WBC. It also precharacterizes the RBC morphology based on the image of the RBC monolayer. By using the overview image, the operator can calculate or estimate the level of PLTs. These preliminary results, that is, the preclassifications, precharacterization and PLT levels are then stored in a database.

A skilled operator, trained in the use of the software and in recognition of blood cells, then opens the order to review and verify (or modify) the preliminary results. The review can be done either at the device or using the CellaVision Remote Review Software (CRRS).

Table 5:1 Parameters reported for CellaVision® DC-1

Parameter	Abbreviation
White blood cells	WBC
Red blood cells	RBC
Platelet	PLT

5.7 Substantial equivalence information

5.7.1 Technological Characteristics Comparison with Predicate

Like the predicate device, CellaVision® DC-1 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 verify 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, CellaVision®DC-1 presents an overview image from which it is possible to characterize red blood cells regarding size, shape and color and count PLTs.

5.8 Principle of operation/comparison with predicate device

The method requires a skilled operator to review the images of the cells as does the predicate device. See attached substantial equivalence comparisons (Table 5:2).

Table 5:2 Comparison with Predicate Device: **similarities**

Characteristic	CellaVision® DC-1	CellaVision® DM1200 K092868
Intended use	CellaVision® DC-1 is an automated cell-locating device intended for in-vitro diagnostic use in clinical laboratories. CellaVision® DC-1 is intended to be used by operators, trained in the use of the device. Peripheral Blood Application: The CellaVision Peripheral Blood Application is intended for differential count of white blood cells (WBC), characterization of red blood cell (RBC) morphology and platelet estimation. The CellaVision® DC-1 with the Peripheral Blood Application automatically locates blood cells on peripheral blood (PB) smears. The application presents images of the blood cells for review. A skilled operator trained in recognition of blood cells, identifies and verifies	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.

Characteristic	CellaVision® DC-1	CellaVision® DM1200 K092868
	the suggested classification of each cell according to type.	
Intended use population	The intended use population is patients whose blood samples have been flagged as abnormal by an automated cell counter.	Same
Analytes	Automated cell-locating device for cell-location and identification of RBC, WBC or platelets for in-vitro use. Verification of results by human operator.	Same
Light source	LED (Light Emitting Diode)	Same
Classification software	CellaVision® DM Software including Peripheral blood application (version 7.0).	CellaVision® DM Software including Peripheral blood application (version 6.0).
Sample type	Stained blood film on glass slides of peripheral whole blood.	Same
Sample preparation	Romanowsky stain	Same
Analysis technique	White blood cells: Cells are located/counted by moving according to the battlement track pattern. Cell images are analyzed using artificial intelligence trained to distinguish between classes of white blood cells. The cell images are preclassified and the operator verifies the suggested classification by accepting or reclassifying the white blood cells. Red blood cells: The device presents an overview image. The cell images are precharacterized and the operator verifies or re-characterizes red	Same

Characteristic	CellaVision® DC-1	CellaVision® DM1200 K092868
	blood cell morphology from the image. Platelets: The device presents an overview image. The operator manually counts and estimates the platelet concentration from the overview image according to a standardized procedure.	
Optical means for magnifying images of white blood cells for observation and interpretation	Individual white blood cells are magnified and imaged on a camera sensor by a microscope. The camera sensor produces images on a screen for view and interpretation (cell class verification).	Same
Viewing of white blood cell images	Individual located white blood cells are presented in an organized manner and observed on a screen.	Same
Classification of white blood cells	White blood cells are pre-classified and presented to the operator. To complete the differential, the operator needs to verify that all located WBCs are correctly classified. All cells must be classified and verified before the order can be signed.	Same
Characterization of the red blood cell morphology	The device pre-characterizes the RBC morphology based on the overview image of the RBC monolayer, followed by the operator's verification or modification of the suggested results.	Same
Estimating the platelet level	From an overview image corresponding to eight high power fields the platelet level is estimated.	Same
Image interpretation requirements	A skilled operator is required to differentiate and finally modify and/or confirm the preclassification/characterization of the located blood cells.	Same
Information transfer from	The system can interact with a laboratory information system (LIS).	

Characteristic	CellaVision® DC-1	CellaVision® DM1200 K092868
instrument to Printer or network	The system will retrieve order data from the LIS and send results back to the LIS.	Same
Result format	The differential proportional count is normally based on 100 white blood cells. The number of WBCs can be modified if required. The result can be presented as an absolute number or as % of total number of WBCs. The result of RBC characterization is presented as a grading for each morphology.	Same
Technological characteristics	The system locates white blood cells, stores digital images of the cells and suggests a cell class for each white blood cell to aid operators in performing the white blood cell differential procedure. The system captures an overview image of the RBC monolayer for RBC characterization. The operator estimates the platelet concentration using the overview image.	Same
Operators competence	The operator is trained in the recognition of blood cells and in the use of the device.	Same
Decision support	The device includes white blood cell reference cells. The operator can add his/her own reference cells.	Same
Calibration	Recommended calibration once a year by a service engineer.	Same

Table 5:3 Comparison with Predicate Device: **differences**

Characteristic	CellaVision® DC-1	CellaVision® DM1200 K092868
Major parts of the system	• Computer module (integrated) • Motorized microscope • Digital color camera • XY stage • Control unit (integrated in camera) • Casing • Database	• System computer (stand- alone) • Motorized microscope • Digital color camera • Robot gripper unit • Control unit • Casing • Database • Immersion oil unit

Characteristic	CellaVision® DC-1	CellaVision® DM1200 K092868
		• Barcode reader
Neural network	Neural network of convolutional type.	Artificial neural network of multiple perception type.
Loading capacity	1 slide	12 slides
Immersion oil application	Manual application	Automatic application

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

Clinical evaluations have been performed to confirm equivalence with the predicate method (DM1200) for differentiation of WBCs, precharaterization of RBCs and estimation of PLTs. In the following sections CellaVision® DC-1 and CellaVision® DM1200 will be denominated DC-1 and DM1200.

5.9.1 Performance data

The following performance data were provided in support of the substantial equivalence determination.

5.10 Electromagnetic compatibility (EMC)

EMC testing was conducted on the DC-1 and Power supply ATS090-P120.
The test showed that the DC-1 is in conformity with IEC 61010-1:2010 and IEC 61010-2-101:2015.

5.11 Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and Staff, "Guidance for the Content of premarket Submissions for Software Contained in Medical Devices." The software application was considered as a "moderate" level of concern, since a malfunction failure or latent design flaw in the software could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that could lead to a minor injury.

5.12 Analytical Performance: Precision, Repeatability

The repeatability studies were conducted in a clinical setting using three different laboratories. The study outline for the three repeatability studies was a so-called 20 x 2 x 2 single-site repeatability study and was based on CLSI EP05-A3 (Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition).

5.12.1 WBC Repeatability

Five samples at each of the sites were selected for the study. All slides were processed on the DC-1 according to the study outline which was a so-called 20 x 2 x 2 single-site repeatability study (total of 80 runs/sample). The evaluation was performed on the preclassified results suggested by the device. The proportional cell count in percent for each cell class was used to estimate total variance and variance components for repeatability (within-run, between-run, between-day and within laboratory) by an ANOVA. All tests except repeatability and within-

laboratory precision on three occasions met acceptance criteria. The three samples all displayed variation in mean values between slide 1 and 2 for the specific cell types, resulting in a variation slightly above acceptance criteria.

The overall results from the WBC repeatability evaluation of the DC-1 at all three sites were successful.

5.12.2 RBC Repeatability

Five samples at each of the sites were selected for the study. All slides were processed on the DC-1 according to the study outline which was a so-called 20 x 2 x 2 single-site repeatability study (total of 80 runs/sample). The evaluation was performed on the precharacterized results suggested by the device. Repeatability in terms of grade (0, 1, 2 or 3) for each morphological characteristic was evaluated. The most prevalent grade reported was evaluated, and the agreement (percentage of runs reporting the grade) was calculated for each morphology. The agreement was evaluated for each slide and run (1st and 2nd daily run, respectively), as well as for each sample. One sample displayed variation in mean value between slide 1 and 2 for the specific cell type, resulting in a variation above acceptance criteria.

The overall results from the RBC repeatability evaluation of the DC-1 at all three sites were successful.

5.12.3 PLT Repeatability

Four samples at each of the sites were selected for the study. All slides were processed on the DC-1 according to the study outline which was a so-called 20 x 2 x 2 single-site repeatability study (total of 80 runs/sample). For each PLT level (significantly decreased, decreased, normal or increased) the agreement (percentage of runs reporting the actual PLT level) was evaluated. The agreement was evaluated for each slide and run (1st and 2nd daily run, respectively) as well as for each sample.

The repeatability of PLT analysis met the acceptance criterion in all samples at all three sites.

5.13 Analytical Performance: Precision, Reproducibility

The reproducibility study was conducted in a clinical setting using three different laboratories. The study outline was a so-called 3 x 5 x 5 multi-site reproducibility study and was based on CLSI EP05-A3 (Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition).

5.13.1 WBC Reproducibility

Five samples were included in the study. Five slides were prepared from each sample and processed every day at each of three study sites for five days (a 3 x 5 x 5 study). The reproducibility analysis was performed on verified data. The proportional cell count in percent for each cell class was used to estimate total variation and variance components for reproducibility by an ANOVA based on CLSI EP05-A3. Evaluation was performed for each cell class per sample as well as per sample and site.

The overall results from the reproducibility evaluation of the DC-1 are considered to be successful.

5.13.2 RBC Reproducibility

Four samples were included in the study. Five slides were prepared from each sample and processed every day at each of three study sites for five days (a 3 x 5 x 5 study). The reproducibility analysis was performed on verified data. Reproducibility in terms of grade (0, 1, 2 or 3) for each morphological characteristic was evaluated. The most prevalent grade reported was evaluated, and the agreement (percentage of runs reporting the grade) was calculated. The agreement was evaluated for each morphology per sample as well as per sample and site.

The overall results from the reproducibility evaluation of the DC-1 are considered to be successful.

5.13.3 PLT Reproducibility

Four samples were included in the study. Five slides were prepared from each sample and processed every day at each of three study sites for five days (a 3 x 5 x 5 study). The operator used the overview image to count the platelets per grid square.
For each PLT level (significantly decreased, decreased, normal or increased) the agreement (percentage of runs reporting the most prevalent level) was calculated for each sample as well as for each sample and site. The reproducibility of the PLT count met the acceptance criterion in all samples.

The overall results from the reproducibility evaluation of the DC-1 are considered to be successful.

5.13.4 Linearity

Not applicable

5.13.5 Carryover

Not applicable

5.13.6 Interfering substance

Not applicable

5.14 Clinical Performance: Method, Comparison

The comparison studies were conducted at three different laboratories for each analyte (WBC, RBC and PLT).

Comparison studies were conducted comparing the DC-1 (test device) with the DM1200 (reference device) for each of the cell types (WBC, RBC and PLT).

Three comparison studies have been performed for each of the cell types (3 for WBC, 3 for RBC and 3 for PLT). The WBC and RBC studies were based on CLSI H20-A2 (RBC, only applicable parts).

5.14.1 WBC Comparison

In total 598 samples (1196 slides, A and B slide) were analyzed on both the DM1200 and on the DC-1 across the three sites. The verified WBC results from the DC-1 were compared to the corresponding results from the DM1200. Accuracy as well as Positive (PPA), Negative (NPA) and Overall Agreement (OA) were determined.

5.14.1.1 Distribution and Morphology

PPA, NPA and OA were calculated for the distributional and morphological results separately.

Table 5:4 Combined results all three sites

Group/Site	Comparison	Results %
Distribution	OA	89,8%
	PPA	89,2%
	NPA	90,4%
Morphology	OA	91,3%
	PPA	88,6%
	NPA	92,5%

5.14.1.2 WBC Accuracy

Accuracy between WBC analysis results from the DC-1 compared to the DM1200 was determined using linear regression. The mean differential counts for individual cell types with a normal level of >5% were analyzed. The slope of the regression line when compared with the reference method should be within 0.8-1.2 with an intercept within ±0.2. The accuracy evaluations were successful in all studies and shows no systematic difference between the DC-1 and the DM1200.

The accuracy agreement for the applicable WBCs (Segmented Neutrophils, Lymphocytes, Eosinophils and Monocytes) were all within the acceptance criteria.

5.14.2 RBC Comparison

In total 586 samples were analyzed on both the DM1200 and on the DC-1across the three sites. The verified RBC results from the DC-1 were compared to the corresponding results from the DM1200.

PPA, NPA and OA with two-sided 95% confidence intervals, comparing the DC-1 results with the DM1200 results, were calculated. The results were assumed to be normally distributed and calculations of 95% confidence intervals have been performed as described in EP-12-A2.

Table 5:5 Combined results all three sites

Group	Comparison	Result (95% CI LL–UL)
Color	OA	79,9% (76,4%-82,9%)
	PPA	87,8% (82,3%-91,8%)
	NPA	76,3% (71,9%-80,2%)
Size	OA	88,2% (85,3%-90,6%)
	PPA	89,8% (86,3%-92,2%)
	NPA	84,8% (79,0%-89,2%)
Shape	OA	85,2%

		(82,0%-87,8%)
	PPA	87,3% (82,3%-91,0%)
	NPA	83,8% (79,6%-87,3%)

5.14.3 PLT Comparison

In total 598 samples were analyzed on both the DM1200 and on the DC-1across the three sites.

The agreement between the two devices on PLT level was evaluated by summarizing the results as outlined in

Table 5:6 below and by calculating the Cohen's Kappa coefficient.

Each level was assigned a number:

1 = Sign. Decreased

2 = Decreased

3 = Normal

4 = Increased

Table 5:6 Agreement per sample

DC-1	**DM1200**				
	Level 1	**Level 2**	**Level 3**	**Level 4**	**Total**
Level 1	140	16	0	0	**156**
Level 2	6	135	13	0	**154**
Level 3	0	10	173	10	**193**
Level 4	0	0	17	78	**95**
Total	146	161	203	88	**598***

***All samples were collected based on the results from cell counters.

Table 5:7 Cohen's Kappa coefficient calculated using Medcalc®

Weighted Kappa*	0,89405
Standard error	0,01196
95% CI	0,87062 to 0,91748

In all three studies the Cohen's Kappa coefficient met the acceptance criterion of ≥0,6.

The conclusion of the evaluations of the PLT estimation analysis is that the agreement requirement is fulfilled.

5.15 Proposed labeling

The labeling satisfies the requirement of 21 CDR Part 809.subpart B.

5.16 Conclusion

The CellaVision® DC-1 analyzer has the same intended use as the predicate device, the CellaVision® DM1200 analyzer cleared in K092868. They are quantitative, automated hematology analyzers for In Vitro Diagnostic Use in clinical laboratories. These analyzers may be used with K2 EDTA or K3 EDTA whole blood. Both analyzers are only to be used by trained medical professionals to identify abnormal parameters of WBC, RBC and PLT. The performance studies of the CellaVision® DC-1 analyzer were conducted per the study protocols agreed by FDA in pre-submission (Q171293) covering all cell types and morphologies that the analyzer is intended to identify. For WBC, the samples studied covered both normal and abnormal levels for band neutrophils, segmented neutrophils, eosinophils, basophils, lymphocytes, and monocytes. Samples with abnormal concentrations of promyelocytes, myelocytes, metamyelocytes, blast cells, variant lymphocytes, plasma cells and NRBC were also included in the study. For RBC, the samples studied covered all morphological characteristics. For PLT, four samples covering the predefined levels were included. The performance comparison study results demonstrated that the CellaVision® DC-1 analyzer is substantially equivalent to the predicate device, the CellaVision® DM1200 analyzer and the few differences do not raise new questions of the safety and effectiveness.

The overall results from both the clinical and analytical evaluations concluded that the studies performed for WBC, RBC and PLT on the CellaVision® DC-1 are considered to be successful.

No adverse events were reported from any of the studies.