510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K200595

B Applicant

CellaVision AB

C Proprietary and Established Names

CellaVision® DC-1, CellaVision® DC-1 PPA

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JOY	Class II	21 CFR 864.5260 - Automated Cell-Locating Device	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

The measurand for CellaVision DC-1 include white blood cells, red blood cells, and platelet.

C Type of Test:

The CellaVision DC-1 facilitates the differential count of white blood cells (WBC), characterization of red blood cell (RBC) morphology and platelet estimation, by capturing and pre-classifying images of WBCs and RBCs on a stained peripheral blood smear, as well as capturing and presenting an overview image of the blood smear for platelet analysis.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

None

IV Device/System Characteristics:

A Device Description:

The CellaVision DC-1 is a cell-locating device. The CellaVision DC-1 consists of a built-in PC with a Solid-State Disk (SSD) containing CellaVision DM Software (CDMS), a high-power magnification focusing nosepiece micrscope 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.

The CDMS is the software that controls the collection of cell images, stores the images of the located cells and the results, and displays the images in an organized manner to the operator.

The Peripheral Blood Application (PBA) is a software module included as part of the CDMS. The PBA performs pre-classification of WBCs, pre-characterization of RBCs, and facilitates platelet estimation by presenting an overview image captured of a monolayer area.

B Principle of Operation:

The typical workflow with respect to the CellaVision DC-1 is as follows.

- From a peripheral blood sample collected in K_2EDTA or K_3EDTA tube, 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 made either manually or by using an automatic slide maker-stainer.

- 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 overview image of a part of the RBC monolayer.

- The device software, PBA, pre-classifies each located WBC. It also pre-characterizes the RBC morphology based on the overview image. By using the overview image, the operator can calculate or estimate the level of PLTs.

- During the review/verification stage, 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).

Instrument Description Information:

1. Instrument Name: CellaVision DC-1

2. Specimen Identification: All slides must be labeled clearly with patient or order information. To use the optional handheld barcode reader, slides must be labeled with a barcode label.

3. Specimen Sampling and Handling: Slides are processed one at a time. To load slide, manually open the input hatch, place the slide, with the blood smear facing up, in the loading tray, and close the hatch.

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

5. Quality Control:

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.

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 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.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Cellavision DM1200 Automated Hematology Analyzer, Model Xu-10127

B Predicate 510(k) Number(s):
K092868

C Comparison with Predicate(s):

Device & Predicate Device(s):	K200595	K092868
Device Trade Name	CellaVision DC-1	CellaVision DM1200
General Device Characteristic Similarities		
Intended Use/Indications 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. 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	CellaVision DM1200 is an automated cell-locating device. CellaVision 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. CellaVision DM1200 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

Device & Predicate Device(s):	K200595	K092868
Device Trade Name	CellaVision DC-1	CellaVision DM1200
	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.	
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.	Same

Device & Predicate Device(s):	K200595	K092868
Device Trade Name	CellaVision DC-1	CellaVision DM1200
	The cell images are precharacterized and the operator verifies or re-characterizes red blood cell morphology from the image. • Platelets: The device presents an overview image (corresponding to eight high power fields). 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	An overview image is collected and presented from which the operator can characterize the red blood cells morphology.	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	Same

Device & Predicate Device(s):	K200595	K092868
Device Trade Name	CellaVision DC-1	CellaVision DM1200
	the located blood cells.	
Information transfer from instrument to Printer or network	The system can interact with a laboratory information system (LIS). 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
General Device Characteristic Differences		
Major parts of the system	• Computer module (integrated) • Motorized microscope • Digital color camera	• System computer (stand-alone) • Motorized microscope • Digital color camera

Device & Predicate Device(s):	K200595	K092868
Device Trade Name	CellaVision DC-1	CellaVision DM1200
	• XY stage • Control unit (integrated in camera) • Casing • Database	• Robot gripper unit • Control unit • Casing • Database • Immersion oil unit • 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

VI Standards/Guidance Documents Referenced:

Guidance Documents

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2014
- Guidance for Industry – Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, January 2005
- Guidance for Industry, FDA Reviewer and Compliance on Off-The-Shelf Use in Medical Devices, September 1999
- General Principles of Software Validation; Final Guidance for industry and FDA Staff, January 2002
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 2005
- Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable - Guidance for Sponsors, Institutional Review Boards, and Food and Drug Administration Staff, April 2006
- Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests - Guidance for Industry and FDA Staff, March 2007

FDA-recognized consensus standards

- ASTM D4169-16 - Standard Practice for Performance Testing of Shipping Containers and Systems (Recognition Number: 14-499)
- AUTO11-A2 - Information Technology Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard - Second Edition (Recognition Number: 13-85)
- CLSI EP05-A3 - Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition, (Recognition Number: 7-251)
- CLSI EP12-A2 - User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition (Recognition Number: 7-152)

- CLSI H20-A2 - Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard - Second Edition, (Recognition Number: 7-165)
- IEC 62366-1:2015 - Medical devices - Part 1: Application of usability engineering to medical devices [Including Corrigendum 1 (2016)], (Recognition Number: 5-114)
- ISO 14155:2011 - Clinical investigations of medical devices for human subject- Good clinical practice, (Recognition Number: 2-205)
- ISO 14971:2007 - Medical devices - Application of risk management to medical devices, (Recognition Number: 5-40)
- ISO 15223-1:2016 - Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements, (Recognition Number: 5-117)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Three repeatability studies were performed for white blood cell (WBC), red blood cell (RBC), and platelet (PLT), respectively to demonstrate the repeatable performance of CellaVision DC-1 across multiple days. Three reproducibility studies were also conducted for WBC, RBC, and PLT to demonstrate that the results generated by the CellaVision DC-1 are reproducible across sites. Each study was conducted at one U.S. site and two sites outside the U.S. The study designs and representative results are summarized below.

i. WBC Pre-classification Repeatability

The repeatability of WBC pre-classification results generated by CellaVision DC-1 was evaluated across multiple days. At each site, the study included five samples, one was normal sample and four displayed various clinical pathological characteristics (i.e. abnormal samples). The study samples were selected from leftover samples from the laboratory's daily workflow. All samples were initially analyzed on an automated cell counter available at the site. Each sample was made into two slides to represent two replicates (i.e. both slides were analyzed once in each run to represent two replicate measurements). Each sample was run twice per day for 20 days, resulting in 20 x 2 x 2 measurements. The proportional cell count in percent for each cell class was used to estimate total variance and variance components for repeatability, including within-run, between-run, between-day, and within-laboratory, by an ANOVA. The WBC results were evaluated separately for each sample and site.

ii. RBC Pre-characterization Repeatability

The repeatability of RBC pre-characterization results generated by CellaVision DC-1 was evaluated across multiple days. At each site, the study included five samples, one was normal sample and four displayed abnormal levels of Polychromatic cells,

Hypochromatic cells, Anisocytosis, Microcytes, Macrocytes, Poikilocytosis (i.e. abnormal samples). The study samples were selected from leftover samples from the laboratory's daily workflow. All five samples were initially analyzed on an automated cell counter available at the site. Each sample was made into two slides to represent two replicates (i.e. both slides were analyzed once in each run to represent two replicate measurements). Each sample was run twice per day for 20 days, resulting in 20 x 2 x 2 measurements. The 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, as well as for each sample. The RBC results were evaluated separately for each site.

iii. PLT Estimation Repeatability

The repeatability of PLT estimation using the overview image captured by the CellaVision DC-1 was evaluated across multiple days. The procedure for estimating PLT concentration with the overview image provided by CellaVision DC-1 includes: 1) First, the overview image is divided into multiple grids and the operator counts the number of platelet in each grid and enters the counted values for all corresponding grids to estimate the concentration of PLT in the sample; 2) Based on the estimated concentration of PLT, the device reports a grade (1 = significant decreased, 2 = decreased, 3 = normal, and 4 = increased) corresponding to the predefined ranges. At each site, the study included four samples, one was normal sample (~250 x 10^9/L) and three abnormal samples, including one significantly decreased (~30 x 10^9/L), one decreased (~100x10^9/L), and one increased (~600 x 10^9/L) samples. The study samples were selected from leftover samples from the laboratory's daily workflow. All four samples were initially analyzed on an automated cell counter available at the site. Each sample was made into two slides to represent two replicates (i.e. both slides were analyzed once in each run to represent two replicate measurements). Each sample was run twice per day for 20 days, resulting in 20 x 2 x 2 measurements. The agreement (i.e. percentage of runs reporting the actual PLT level) was evaluated for each PLT level. The PLT results were evaluated separately for each site.

iv. WBC Reproducibility

A three-site reproducibility study was conducted to demonstrate that the WBC results obtained from using the CellaVision DC-1 were reproducible across multiple sites (devices). The study included five samples, one was normal sample and four displayed various clinical pathological characteristics (i.e. abnormal samples). The study samples were selected from leftover samples from the laboratories' daily workflow. All five samples were initially analyzed on an automated cell counter. Each sample was made into five slides to represent five replicates (i.e. five slides were analyzed once in each run to represent five replicate measurements) that were run once per day for five days per site, resulting in 3 x 5 x 5 measurements in total. In the primary analysis, the operator-verified results, including the proportional cell count in percent for each cell class, were used to estimate total variation and variance. In addition to analyzing the operator-verified

results, a secondary analysis was performed on the preclassification outputs generated by the CellaVision DC-1 (i.e. without operator verification).

v. RBC Reproducibility

A three-site reproducibility study was conducted to demonstrate that the RBC results obtained from using the CellaVision DC-1 were reproducible. The study included four samples, one was normal sample and three displayed abnormal levels of Polychromatic cells, Hypochromatic cells, Anisocytosis, Microcytes, Macrocytes, Poikilocytosis (i.e. abnormal samples). The study samples were selected from leftover samples from the laboratory's daily workflow. All four samples were initially analyzed on an automated cell counter available at the site. Each sample was made into five slides to represent five replicates (i.e. five slides were analyzed once in each run to represent five replicate measurements). The slides were run once per day for five days per site, resulting in 3 x 5 x 5 measurements in total. 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.

vi. PLT Reproducibility

A three-site reproducibility study was conducted to demonstrate that the PLT results obtained from using the overview image provided by CellaVision DC-1 were reproducible. The study included four samples, one was normal sample (~250x10^9/L) and three abnormal samples, including one significantly decreased (~30x10^9/L), one decreased (~100x10^9/L), and one increased (~600x10^9/L) samples. The study samples were leftover samples selected from different laboratories' daily workflow. All four samples were initially analyzed on an automated cell counter. Each sample was made into five slides to represent five replicates (i.e. five slides were analyzed once in each run to represent five replicate measurements) that were run once per day for five days per site, resulting in 3 x 5 x 5 measurements in total. For each PLT level (significantly decreased, decreased, normal or increased) the agreement (i.e. percentage of runs reporting the actual PLT level) was evaluated. The agreement was evaluated for each sample and site and representative results by sample are presented below.

Agreement (%) per sample

Sample	Level 1	Level 2	Level 3	Level 4	Total number of runs (n)	Agreement %
1	0	0	1	74	75	98.6
2	0	75	0	0	75	100
3	75	0	0	0	75	100
4	0	2	73	0	75	97.3

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

   Not applicable.

4. Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Not applicable.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Not applicable.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Three multi-site method comparison studies were conducted for WBC, RBC, and PLT, respectively to demonstrate that the CellaVision DC-1 (DC-1) performs equivalently to the predicate device, CellaVision DM1200 (DM1200). Each study involved three sites, one of which was a U.S. site. A total of seven sites participated in the three studies.

   i. WBC Comparison

   A total of 598 samples were analyzed on both the DM1200 and on the DC-1. The samples were leftover samples from the laboratory´s daily workload. Each site collected approximately 200 samples, 100 of which were normal (non-diseased) and 100 were samples with various clinical pathological characteristics (abnormal samples). Normal and abnormal samples were defined in accordance with CLSI H20-A2. The samples covered a wide range of ages and both genders. Three slides (A, B, and Spare) were prepared from each sample and stained using Romanowsky stain as per standard clinical practice. The operator-verified WBC results from the DC-1 were compared to the

corresponding results from the DM1200. The results of one slide (slide A) from the DC-1 were compared to the mean results (slide A and slide B) from the DM1200, also known as the single slide evaluation.

WBC Evaluation

In this evaluation, the results from one slide per sample (slide A) from the DC-1 were compared to the mean results (slides A and B) from the DM1200. This evaluation was referred to as the duplicate slide evaluation.

DC-1 slide A versus DM1200 mean: Total Distribution Agreement

	DM1200 Positive	DM1200 Negative	Total
DC-1 Positive	259	32	291
DC-1 Negative	47	260	307
Total	306	292	598

	Result	95% CI	
		LL	UL
OA	86.8%	83.8%	89.3%
PPA	84.6%	80.2%	88.2%
NPA	89.0%	84.9%	92.1%

DC-1 slide A versus DM1200 mean: Total Morphology Agreement

	DM1200 Positive	DM1200 Negative	Total
DC-1 Positive	162	48	210
DC-1 Negative	22	366	388
Total	184	414	598

	Result	95% CI	
		LL	UL
OA	88.3%	85.5%	90.6%
PPA	88.0%	82.6%	92.0%
NPA	88.4%	85.0%	91.1%

Regression analysis was performed for WBC classes that have normal range of 5% or more, comparing slide A results from DC-1 to mean results from DM1200. Segmented Neutrophils, Lymphocytes, Eosinophils, and Monocytes were included in this analysis. The fit results are summarized below.

Cell Type	Regression Fit	R^2
Segmented Neutrophils	Y = 0.9926X + 0.0027	0.969
Lymphocytes	Y = 0.9799X + 0.0017	0.946
Eosinophils	Y = 0.9884X + 0.0014	0.928
Monocytes	Y = 0.9838X + 0.0025	0.897

ii. RBC Comparison

A total of 586 slides (one slide per sample) were analyzed on both the DC-1 and the DM1200 across three sites. The samples were leftover samples from the laboratory´s daily workload. Each site collected approximately 200 samples, with 50 samples for each group: normal, color (Polychromasia, Hypochromasia), size (Anisocytosis, Microcytosis, Macrocytosis) and shape (Poikilocytosis). The samples covered a wide range of ages and both genders. The slides were divided into four sets, one for each operator (e.g. 50 slides in each). Each of the operators verified their own allocated slides on both the DM1200 and the DC-1.

The RBCs were characterized for each morphology according to a predefined 4-graded scale (normal (0), slight (1), moderate (2) or marked (3)). The operator-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 were performed as described in CLSI EP12-A2. The overall agreement results for each group are presented below.

Morphology reference limits

Group	RBC characteristics	Abnormal grade
Color	Polychromatic cells	≥1
	Hypochromatic cells	≥2
Size	Anisocytosis	≥1
	Microcytes	≥1
	Macrocytes	≥2
Shape	Poikilocytosis	≥1

Color: DC-1 versus DM1200

	DM1200 Positive	DM1200 Negative	Total
DC-1 Positive	159	96	255
DC-1 Negative	22	309	331
Total	181	405	586

	Result	95% CI	
		LL	UL
OA	79.9%	76.4%	82.9%
PPA	87.8%	82.3%	91.8%
NPA	76.3%	71.9%	80.2%

Size: DC-1 versus DM1200

	DM1200 Positive	DM1200 Negative	Total
DC-1 Positive	354	29	383
DC-1 Negative	40	162	202
Total	394	191	585*

*One sample was excluded due to missing grading information for Microcytes.

	Result	95% CI	
		LL	UL
OA	88.2%	85.3%	90.6%
PPA	89.8%	86.3%	92.2%
NPA	84.8%	79.0%	89.2%

Shape: DC-1 versus DM1200

	DM1200 Positive	DM1200 Negative	Total
DC-1 Positive	199	58	257
DC-1 Negative	29	300	329
Total	228	358	586

	Result	95% CI	
		LL	UL
OA	85.2%	82.0%	87.8%
PPA	87.3%	82.3%	91.0%
NPA	83.8%	79.6%	87.3%

RBC Supplemental Study: DC-1 versus manual light microscope

To supplement the results for the Color group, the sponsor conducted a study in which results for the group Color from the DC-1 were compared to the results from manual light microscope. An experienced operator analyzed 70 slides made up of normal and abnormal (polychromatic and hypochromatic) samples on both the DC-1 and the manual light microscope with a wash-out period between the two devices. The results are summarized below.

Color: DC-1 versus Manual Light Microscope

	MLM Positive	MLM Negative	Total
DC-1 Positive	19	10	29
DC-1 Negative	0	41	41
Total	19	51	70

	Result	95% CI	
		LL	UL
OA	85.7%	75.7%	92.0%
PPA	100%	83.2%	100%
NPA	80.4%	67.5%	89.0%

iii. PLT Comparison

A total of 598 slides were analyzed on both the DC-1 and the DM1200 across three sites. The samples were leftover samples from the laboratory´s daily workload. Each site

collected 200 samples (50 from each PLT level based on cell counter results). The samples covered a wide range of patient demographics. All samples were collected based on the results from the automated cell counters. Each level was assigned a number: 1= Significant Decreased, 2= Decreased, 3=Normal, 4=Increased. PPA, NPA and OA for each PLT level were calculated by using 2x2 contingency tables. The 95% confidence intervals were calculated according to CLSI EP12-A2.

PLT analysis between the DC-1 device and the DM1200

Site	Agreement	Level 2 (95% CI)	Level 3 (95% CI)	Level 4 (95% CI)
All combined n=598	OA	96.3% (94.5%, 97.6%)	96.2% (94.3%, 97.4%)	95.5% (93.5%, 96.9%)
	PPA	95.9% (91.3%, 98.1%)	96.7% (94.1%, 98.2%)	96.7% (94.7%, 97.9%)
	NPA	96.5% (94.3%, 97.8%)	95.5% (92.5%, 97.4%)	88.6% (80.3%, 93.7%)

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

F Other Supportive Instrument Performance Characteristics Data:

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.