

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

A. 510(k) Number:

K040591

B. Manufacturer and Instrument Name:

BioView, Ltd., Duet™ System

C. Type of Test or Tests performed:

Detection of amniotic fluid cells stained by FISH

D. System Descriptions:

1. Device Description:

The Duet System is a fully integrated imaging and scanning platform designed to enable identification and examination of cells of interest using a special dual-scan process. Cytological analysis experts can scan any slide, using both bright field and fluorescent illumination. While each type of scanning can be run by the Duet system independently, Duet has the ability to run both types of scans on the same slide, without losing the important data from either of the scans. Captured images from the first scan are saved as a “historical record” and can then be used for comparison during the second scanning stage. The images can be displayed side-by-side in a gallery of captured snapshots, referred to as targets.

2. Principles of Operation:

The Duet System is software controlled and includes features such as: acquisition of images, views, editing, relocation, enhancement capabilities, automatic/manual counting and classification, printing, export of images and backups. The Duet System can also scan each field of view with several fluorescent filters instead of only one, generating and displaying a combined image for each field of view.

3. Modes of Operation:

- a. Automatic scanning provides a gallery of targets that the system captures for all identified fields.
- b. Manual scanning provides interactive control over the microscope. This enables a user-controlled scan of any slide under either bright field or fluorescent illumination.

4. Specimen Identification:

Individual specimen slide case details are entered in a Slide Configuration dialog box where case details and a name are assigned to a slide. The scan process (fluorescent or brightfield), mode of scanning (automatic or interactive), scan task, and scan program (coordinates) details are entered.

5. Specimen Sampling and Handling:

Standardized cell preparations on peripheral blood and bone marrow specimens are applied to microscope slides.

6. Calibration:
Calibration is recommended at least once every 6 months by Bio View service personnel.
7. Quality Control:
N/A
8. Software:
FDA has reviewed the applicant's Hazard Analysis and software Documentation: Yes X or No

E. Regulatory Information:

1. Regulation Section:
21 CFR 864.5260, Automated cell-locating device
2. Classification:
Class II
3. Product Code:
JOY
4. Panel:
81 (Hematology)

F. Intended Use:

1. Indication(s) for Use:
The Duet System is an automated scanning microscope and image analysis system. It is intended for in-vitro diagnostic use as an aiding tool to the pathologist in the detection, classification and counting of cells of interest based on color, intensity, size, pattern, and shape. The Duet System is intended to detect the following cell types: 1. Hematopoietic cells stained by Giemsa stain, Immunohistochemistry or ISH (with bright field and fluorescent) prepared from cell suspension; 2. Amniotic cells stained by FISH (using direct labeled DNA probes for chromosomes X, Y, 13, 18, and 21).
2. Special Condition for use Statement(s):
NA

G. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) numbers:
 - a. BioView Duet™ System (k030192)
 - b. Applied Spectral Imaging (k012103)
2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use	Same	Same
Cell Source	Peripheral blood, bone marrow, and amniotic fluid	Peripheral blood, bone marrow
Preparation Techniques	Same	Same
Equipment and Accessories	Same	Same
Differences		
Item	Device	Predicate
Indications for Use	Hematopoietic cells and amniotic fluid cells	Hematopoietic cells
Microscope Fluorescent Filters	Dapi/FITC/TRITC (Triple) CFP/YFP/DsRed (Aqua-orange-green) FITC/RSGFP/Bodipy/Fluo 3/DiO (Green) Cy3.5™ (Red)	Dapi/FITC/TRITC (Triple)

H. Standard/Guidance Document Referenced (if applicable):

NCCLS EP5-A, Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline.

I. Performance Characteristics:

1. Analytical Performance:

- a. *Accuracy:* A set of 133 slides of amniotic fluid cells were examined two ways: 1. routine manual test, done by an expert; 2. Analysis using the Duet System. During the tests the overall percentage of normal cells was recorded for each test. The differences between the findings by using the Duet and the routine manual reading were calculated and were analyzed to evaluate the bias between the two methods and to see whether there is a statistical difference between the two sets of corresponding findings.

- The Slope and intercept of the fitted linear regression line are 0.9758 and 2.2316 respectively.
- N= 132
- The range of data is from 17.45% to 100%.
- The comparative method used in the regressions is manual scoring of cells.
- Individual observations were used in the regressions for both comparative method and test method.
- The method used to fit the linear regression was ordinary least squares.

- b. *Precision/Reproducibility:* For amniotic cells the study included a set of four slides. Each slide was analyzed on three different systems, and three times on one of these systems. The study was done over a period of 17 days. The summarized result of the variance analysis is presented in the following table:

Source of Variation	Sum of Square	DF	Mean Square	F	Significance Level
Between Samples	213.1160	3	71.0387		
Within Samples	1.1583	8	0.1448		
Between Measures	0.5305	2	0.2652	2.5346	0.1593
Residual	0.6279	6	0.1046		
Total	214.274	11	19.4795		

There was no statistical difference between the three runs on the same Duet System (P value=0.1593>0.05). The three runs on the same Duet System were analyzed and the CV between the readings was calculated to be 0.15%. The final conclusion of the study is that there was no significant difference between inter and intra instrument precision.

- c. *Linearity:*
N/A
- d. *Carryover:*
N/A
- e. *Interfering Substances:*
N/A

2. Other Supportive Instrument Performance Data Not Covered Above:
N/A

J. Conclusion:

The submitted information in this premarket notification is complete to support a substantial equivalence decision.