

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
INSTRUMENT ONLY TEMPLATE**

**A. 510(k) Number:**

K071398

**B. Purpose for Submission:**

Traditional 510(k)

**C. Manufacturer and Instrument Name:**

Applied Spectral Imaging Ltd. (ASI)

**D. Type of Test or Tests Performed:**

The ScanView is indicated to detect the following cell types: CEP X Spectrum Orange/CEP Y Spectrum Green DNA Probe Kit (Vysis, Inc. Downer's Grove, IL) and is limited to the analysis of CEP XY probes via high magnification capture and analysis of interphase nuclei.

**E. System Descriptions:**

1. Device Description:

The ScanView System is an integrated digital imaging system comprising an external microscope, motorized multi-slide stage, camera, and a workstation. It is designed to acquire images of cells and enables identification and examination of cells of interest. Cytogenetics experts can view and scan cells and record the images using both bright field and fluorescent illumination. The acquired images can be enhanced, archived, retrieved, and printed. The automated microscope also includes a motorized filter turret containing fluorescence filters.

2. Principles of Operation:

The ScanView system works with bright field and fluorescent samples with all currently applied staining techniques. The system transfers images of cells from the microscope to a computer where it is analyzed and processed. The operator with the support of the ScanView software views the images. The results are interpreted by a competent cytogeneticist who exercises his judgment in the use of the provided information when formulating the diagnosis. The results are documented in hard copy and archive.

3. Modes of Operation:

a. Fully Automated Scan and Relocation; b. Image Acquisition and Semi-automatic Relocation; c. Automatic Scanning and Semi-automatic Relocation on Remote Stations; d. Finding Metaphases in a SKY Slide; e. Finding Metaphases in a Multi-color FISH Sample; f. Fluorescence Multi-color FISH Samples-Dual Scan.

4. Specimen Identification:

Manual keyboard entry into a Case Data Manager.

5. Specimen Sampling and Handling:

ScanView scans patient specimen slides stained with the CEP X Spectrum Orange / CEP Y Spectrum Green DNA Probe Kit (Vysis, Inc.).

6. Calibration:

Factory calibrated

7. Quality Control:

ProbeCheck slides, supplied by Vysis, are designed for use as controls for interphase FISH and laboratory quality control, specifically, for the CEP X/Y IVD Kit. ProbeCheck Low Level Male Control Slides (95% XX, 5% XY) and ProbeCheck Low Level Female Control Slides (95% XY, 5% XX) are tested and optimized for use in FISH assays. These slides are manufactured from a mixture of cultured normal male and female lymphoblast cell lines.

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes  or No

**F. Regulatory Information:**

1. Regulation section:

21 CFR 866.4700, Automated fluorescence in situ hybridization (FISH) enumeration systems.

2. Classification:

Class II

3 Product code:

NTH

4. Panel:

Immunology (82)

**G. Intended Use:**

1. Indication(s) for Use:

The ScanView 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 or cytogeneticist in the detection, classification and enumeration of cells of interest based on color, intensity, size, pattern, and shape. The ScanView is indicated to detect the following cell types: CEP® X Spectrum Orange™/CEP® Y Spectrum Green™ DNA Probe Kit (Vysis, Inc., Downer’s Grove, IL) and is limited to the analysis of CEP XY probes via high magnification capture and analysis of interphase nuclei. CEP XY is indicated for use to assess the effectiveness of bone marrow transplantation in opposite-sex transplants

2. Special Conditions for Use Statement(s):

NA

**H. Substantial Equivalence Information:**

1. Predicate Device Name(s) and 510(k) numbers:

a. Applied Spectral Imaging, FISHView, K050236

b. Applied Imaging, CytoVision, K042542

2. Comparison with Predicate Device:

| Similarities       |                       |                  |
|--------------------|-----------------------|------------------|
| Item               | Device                | Predicate        |
| Automated Scanning | Yes                   | CytoVision: Yes  |
| Device Components  | Automated Microscope. | CytoVision: Same |

| <b>Similarities</b>  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                  |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| Item                 | Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Predicate        |
| Constraints          | <p>PC with windows based-based operating system. Keyboard and control panel. Color monitor for display of information. CCD Camera. Motorized Stage.</p> <p>Reliance on automatic scanning and on the expertise and judgment of the cytogenetics technician for cell selection, editing, examination, and correction. All final diagnoses must be made by qualified medical personnel using all information available from the clinical evaluation and other diagnostic procedures.</p> <p>The system does not suggest an interpretation, diagnosis, or treatment.</p> <p>The operator should adhere to the standard safety procedures employed when handling biological substances, glass microscope slides, and electronic equipment.</p> | CytoVision: Same |
| Software Application | <p>Control of the man-machine-interface.</p> <p>Scan, Review, Capture, and Analysis of the images.</p> <p>Handling the images</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | CytoVision: Same |

| <b>Similarities</b> |                                                         |                  |
|---------------------|---------------------------------------------------------|------------------|
| <b>Item</b>         | <b>Device</b>                                           | <b>Predicate</b> |
| Spatial resolution  | display, storage, and communication.<br><br>1280 X 1024 | FISHview: Same   |

| <b>Differences</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Item</b>        | <b>Device</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Predicate</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Indication for Use | <p>The ScanView System is an automated microscope and image analysis system. It is intended for in-vitro diagnostic use as aiding tool to the pathologist or cytogeneticist in the detection, classification and enumeration of cells of interest based on color, intensity, size, pattern, and shape. The ScanView is indicated to detect the following cell types: CEP® X Spectrum Orange™/CEP® Y Spectrum Green™ DNA Probe Kit (Vysis, Inc., Downer's Grove, IL) and is limited to the analysis of CEP XY probes via high magnification capture and analysis of interphase nuclei. CEP XY is indicated for use to assess the effectiveness of bone marrow transplantation in opposite-sex transplants.</p> | <p>The FISHView system is intended to be used for karyotyping with real-time microscope images from cultured and stained cell specimens in their metaphase. The system works with bright field and fluorescent samples. Specimens suitable for banding analysis are: amniotic fluid, chorionic villus, bone marrow and solid tumor. Karyotyping is normally applied for the pre and postnatal diagnosis of birth defects, chromosome abnormalities, genetic diseases (such as Down's Syndrome), cancer and for the follow up of cancer treatment. The FISHView system does not locate metaphase spreads; it does not rank the given according to quality; nor does it automatically classify chromosomes. In addition, the FISHView is intended as an aiding tool to the pathologist or cytologist for digital visualizing, processing,</p> |

| <b>Differences</b> |        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Item               | Device | Predicate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|                    |        | <p>counting, and classification of stained cells and for storage of FISH multi-dye images of the following specimens: amniotic fluid, peripheral blood, chorionic villus, bone marrow and solid tumor. The FISHView does require and relies on the operator to analyze the digitized microscope images.</p> <p>The CytoVision system is an automated scanning microscope and image analysis system. It is intended for in vitro diagnostic use as an aid in chromosomal analysis. CytoVision assists in the location of interphase and metaphase nuclei on standard microscope slides using both brightfield and fluorescent microscopy. This particular CytoVision software application (CEP XY_ENG) is an accessory to the CEP® X Spectrum Orange™/CEP® Y Spectrum Green™ DNA Probe Kit (Vysis, Inc., Downer's Grove, IL) and is limited to the analysis of CEP XY probes via high magnification capture and analysis of interphase nuclei. CEP</p> |

| <b>Differences</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Item               | Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Predicate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Device components  | Motorized stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | XY is indicated for use to assess the effectiveness of bone marrow transplantation in opposite-sex transplants.<br><br>FISHView: no motorized stage.                                                                                                                                                                                                                                                                                                                                                                                                               |
| Constraints        | <p>Reliance on automatic scanning and on the expertise and judgment of the cytogenetics technician for cell selection, editing, examination, and correction. All final diagnoses must be made by qualified medical personnel using all information available from the clinical evaluation and other diagnostic procedures.</p> <p>The system does not suggest an interpretation, diagnosis, or treatment.</p> <p>The operator should adhere to the standard safety procedures employed when handling biological substances, glass microscope slides, and electronic equipment.</p> | <p>FISHView: Reliance on the expertise and judgment of the cytogenetics technician for cell selection, editing, examination, and correction. All final diagnoses must be made by qualified medical personnel using all information available from the clinical evaluation and other diagnostic procedures.</p> <p>The system does not suggest an interpretation, diagnosis, or treatment.</p> <p>The operator should adhere to the standard safety procedures employed when handling biological substances, glass microscope slides, and electronic equipment.</p> |
| Automated scanning | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | FISHView: No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Spatial resolution | 1280 x 1024                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | CytoVision: Not known.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

## I. Special Control/Guidance Document Referenced (if applicable):

Class II Special controls Guidance document: Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems. May 23, 2005.

## J. Performance Characteristics:

### 1. Analytical Performance:

#### a. Accuracy:

Measurements of 61 slides (bone marrow samples from leukemic patients at different post-transplant periods, starting from 7 days up to 2 years and more) using the manual gold standard were compared to results obtained by the ScanView XY System. Regression of manual results on Scan results indicated that:

- Scan and Manual are highly related with R-squares of 0.997, 0.997, and 0.980 for XY-percent, XX-percent, and their ratio respectively.
- The slopes of the Manual-Scan regressions did not differ significantly from 1.0 for all three parameters.
- The intercepts of the Manual-Scan regressions did not differ significantly from 0 for all three parameters.

#### b. Precision/Reproducibility:

For the reproducibility study, 5 slides from 5 different patients were chosen randomly from the 61 slides mentioned in the accuracy section above. In addition, 5 Vysis ProbeCheck control slides were also used to test reproducibility. ProbeCheck Low Level Male Control Slides (95% XX, 5% XY) and ProbeCheck Low Level Female Control Slides (95% XY, 5% XX) were tested. Reproducibility standard deviations for XY-percent, XX-percent and their Ratio were all 3.3% and below. Using these data a statistical model was constructed from which population standard deviations were estimated. The modeled standard deviations for XY-percent, XY-percent, and their Ratio ranged between 0.02% and 0.99%.

#### d. Carryover:

N/A

*e. Interfering Substances:*

N/A

2. Other Supportive Instrument Performance Data Not Covered Above:

N/A

**K. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**L. Conclusion:**

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

