510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k101291

B. Purpose for Submission:
Addition to the ScanView System of fluorescence in situ hybridization (FISH) enumeration of the HER-2/neu gene for human breast cancer specimens

C. Manufacturer and Instrument Name:
Applied Spectral Imaging, Ltd., ScanView System

D. Type of Test or Tests Performed:
Automated fluorescence in situ hybridization (FISH) enumeration of the HER-2/neu gene in human breast cancer specimens (Vysis® PathVysion™ HER-2 DNA Probe kit).

E. System Descriptions:

1. Device Description:
   The ScanView is an integrated digital imaging system constructed of 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. Pathologists can view and scan cells and record the image, using both bright field and fluorescent illumination. The acquired images can be enhanced, archived, retrieved and printed. The automated microscope enables Z motion of the slide and the motorized stage enables its X-Y motions. The microscope also included motorized filter turret containing fluorescence filters.
2. Principles of Operation:
   The ScanView system works with fluorescence in situ hybridization (FISH) stained human breast cancer tissue specimens by the Vysis® PathVysion™ HER-2 DNA Probe kit. The user defines the regions containing tumor cells and manually captures cells from these regions. The system automatically defines the cells of interest and the pathologist then either chooses specific cells for analysis or the system analyzes all of the cells from the selected regions. The red and green signals and the ratio for each cell alone with the average amplification level are calculated. The data are then presented to the pathologist for review. Each cell is displayed in a gallery and the pathologist can reject any one of the cells or modify its classification. The overall statistics are updated accordingly and only at the end of this process, after the pathologist confirms the final score, is the calculated amplification level printed out in a final report.
3. Modes of Operation:
   Semi-automated; manual capture with computer-assisted interpretation
4. Specimen Identification:
   Manual keyboard entry into a Case Data Manager.
5. Specimen Sampling and Handling:
   Specimens are formalin-fixed paraffin embedded human breast cancer tissues hybridized with the Vysis® PathVysion™ HER-2 DNA Probe Kit.
6. Calibration:
   Calibration is performed at the time of installation.

7. Quality Control:
   Control slides are prepared and run concurrently with patient slides according to the Vysis® PathVysion™ HER-2 DNA Probe kit Instructions. The control slides are tested on the ScanView System according to the same procedure as patient slides. It is the responsibility of the pathologist to make assure the control slides meet quality acceptance criteria.
8. Software:
   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:
   Yes____X___ or No_____

F. Regulatory Information:

1. Regulation section:
   866.4700, Automated fluorescence in situ hybridization (FISH) enumeration systems
2. Classification:
   Class II
3 Product code:
   NTH, system, automated scanning microscope and image analysis for fluorescence in situ hybridization (FISH) assays
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:

   1. CEP® X Spectrum Orange™/CEP® Y Spectrum Green™ DNA Probe kit (Abbott Laboratories, Illinois, U.S.A.) 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. Human breast cancer containing the HER-2/neu gene labeled in Red and the centromere of chromosome 17 labeled in Green via fluorescence in situ hybridization (FISH) in interphase nuclei from formalin-fixed, paraffin embedded human breast cancer tissue specimens with Vysis® PathVysion™ HER-2 DNA Probe kit.

   The Scan View System is to be used as an adjunctive automated enumeration tool in conjunction with manual visualization.

2. Special Conditions for Use Statement(s):
   For Prescription Use Only.

H. Substantial Equivalence Information:

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

BioView Ltd., Duet System, K061602
Applied Spectral Imaging, ScanView System, K071398

2. Comparison with Predicate Device:

Similarities			
Item	Device ScanView System	Predicates	
		Duet System K061602	ScanView System K071398
Indications for Use	Human breast cancer containing the HER-2/neu gene labeled in Red and the centromere of chromosome 17 labeled in Green via fluorescence in situ hybridization (FISH) in interphase nuclei from formalin-fixed, paraffin embedded human breast cancer tissue specimens with Vysis® PathVysion™ HER-2 DNA Probe kit.	Detect and quantify Chromosome 17 and the Her-2/neu gene via fluorescence in-situ hybridization (FISH) in interphase nuclei from formalin-fixed, paraffin embedded human breast cancer tissue specimens, probed by the Vysis® PathVysion™ Her-2 DNA Probe Kit. The Duet™ is to be used as an adjunctive enumeration tool, in conjunction with manual visualization, to assist in determining HER-2/neu gene to chromosome 17 signal ratio.	Not applicable.
Probe Kit	Vysis PathVysion® HER-2 DNA Probe Kit	Same	Not applicable.
Device Components	Automated microscope, PC, keyboard and control panel, color monitor, CCD Camera, and motorized stage	Same	Same
Spatial resolution	1280 x 1024	Not known	1280 x 1024
Detection Method	FISH	Same	Same

Differences			
Item	Device	Predicates	
		Duet System K061602	ScanView System K071398
Indications for Use	Human breast cancer containing the HER-2/neu gene labeled in Red and the centromere of chromosome 17 labeled in Green via fluorescence in situ hybridization (FISH) in interphase nuclei from formalin-fixed, paraffin embedded human breast cancer tissue specimens with Vysis® PathVysion™ HER-2 DNA Probe kit.	Not applicable.	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 interphse nuclei. CEP XY is indicated for use to assess the effectiveness of bone marrow transplantation in opposite-sex transplants.

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

"Class II Special Controls Guidance Document: Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems" 23 May 2005.
CLSI Guideline document EP9-A2: "Method Comparison and Bias Estimation Using Patient Samples: Approved Guideline-Second Edition".
Guidance for Industry and FDA Staff: "Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests"; March 2007.
"Guidance for the Content of Premarket Submission for Software Contained in Medical Device", CDRH, May 2005.

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy:

A method comparison study was conducted at three clinical sites: 47 slides from site 1, 34 slides from site 2, and 45 slides from site 3 for a total of 126 slides. Measurements of the 126 slides using results obtained from the Scan View HER-2 FISH System were compared to the manual method.

Summary of Results (ScanView System versus Manual Method)

		Manual Method		
		<1.8	**1.8 to 2.2**	**>2.2**
ScanView Method	**<1.8**	74	2	0
	1.8 to 2.2	0	16	0
	>2.2	0	0	34

Total agreement was 98.4% (124/126) with 95% CI (96%-100%). Negative (<1.8) percent agreement was 100% (74/74) with 95% CI (99%-100%, borderline (1.8-2.2) percent agreement was 88.9% (16/18) with 95% CI (74%-100%) and positive (>2.2) percent agreement was 100% (34/34) with 95% CI (97%-100%).

b. Precision/Reproducibility:

A panel of 6 slides: 2 negative (<1.8), 2 borderline (1.8-2.2), and 2 positive (>2.2), was used to access precision and reproducibility. Three replicates for each slide were tested for within day/within instrument and between day precision and between instrument (site-to-site) reproducibility. Coefficients of Variation (CVs) were acceptable. The results are presented below:

Slide No	**Manual**	**Within day/within instrument**			**Between instruments**			**Between day**		
		Mean	**CV**	**Std Dev**	**Mean**	**CV**	**Std Dev**	**Mean**	**CV**	**Std Dev**
1	**2.02**	1.93	0.04	0.076	1.99	0.03	0.059	1.96	0.008	0.015
2	**2.10**	1.95	0.066	0.129	2.03	0.018	0.036	1.98	0.023	0.046
3	**1.27**	1.13	0.102	0.115	1.20	0.046	0.055	1.16	0.022	0.026
4	**1.38**	1.09	0.16	0.182	1.16	0.036	0.042	1.16	0.015	0.017
5	**5.70**	5.82	0.049	0.285	5.95	0.01	0.062	5.92	0.025	0.149
6	**4.10**	4.23	0.07	0.295	4.12	0.026	0.107	4.20	0.045	0.191

c. Linearity:

Not applicable.

d. Carryover:

Not applicable.

e. Interfering Substances:

Not applicable.

2. Other Supportive Instrument Performance Data Not Covered Above:

Not applicable

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.