Applied Spectral Imaging
Bringing Details to Light

FEB 7 2013

510(k) Summary

As required by section 807.92(c).
February 5, 2013

A. 510(K) Number

K122554

B. Purpose for Submission

Addition of the GenASIs ALK System Application to the GenASIs ScanView System (former name ScanView System).
The GenASIs ALK System Application is to perform automated fluorescence in situ hybridization (FISH) detection and enumerationfor the Vysis® ALK (Anaplastic Lymphoma Kinase) Break Apart FISH Probe kit (List No. 06N38-020). The ALK Break Apart FISH Probe is FDA approved (P11012) and is designed to detect rearrangements involving the ALK gene (2p23) via fluorescence in situ hybridization (FISH) in formalin-fixed paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) tissue specimens to aid in identifying those patients eligible for treatment with XALKORI® (crizotinib).

C. Manufacturer and Instrument Name

C.1. Device Name

GenASIs ScanView System
GenASI ALK System Application

C.2. Submitter's name

Name: Applied Spectral Imaging Ltd.
2 Ha Carmel St, New Industrial Zone, Yokneam 20691, Israel
Tel: (972) 4 6547567, Fax: (972) 4 6547507

C.3. Submission contact person

Ilan Sharon
P.O.B. 4414 (A-109), Caesarea 30889, Israel
TEL: 972-52-8704904

D. Type of Test or Tests Performed

Performing automated fluorescence in situ hybridization (FISH) analysis for samples stained with Vysis ALK Break Apart FISH Probe Kit (List No. 06N38-020) to detect rearrangements involving the ALK gene (2p23) via fluorescence in situ hybridization (FISH) in formalin-fixed paraffin-embedded tissue specimen (FFPE). The test is aimed for analysis of non-small cell lung cancer (NSCLC) tissue specimens, to aid in identifying those patients eligible for treatment with XALKORI® (crizotinib).

E. System Descriptions

Device description:

The GenASIs ScanView System 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. Experts 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 includes motorized filter turret containing fluorescence filters.

The system is designed to work with a manual or automated microscope and includes a dedicated, high powered microscope camera combined with state-of-the-art image analysis software for clinical and research oriented image analysis.

The system's modular platform enables automation of a wide range of laboratory selected assays in pathology and cytogenetics applications. This flexible solution may be adapted to the advanced automation and workflow needs of any laboratory or research institution. The system includes a fully automated computer-controlled microscope, motorized 9-slide stage and high powered microscope-camera. This platform also comes with a variety of additional components such as oil dispenser, automated fluorescent illumination control and state-of-the-art image analysis software for clinical and research oriented image analysis and automatic robotic slide loading system, enabling high throughput automated slide analysis for a wide range of pathology applications that provides a true "walk-away" functionality, scanning up to 81 slides consecutively without human intervention. These scanning capabilities presented with the GenASIs High Throughput platform offer an efficient way to optimally use the scanning and analysis system for uninterrupted scanning.

F. Regulatory Information

Device Classification

Product Code:	NTH
CFR section:	21 CFR 866.4700
Regulation name:	Immunology
Trade Name:	GenASIs ALK System
Common Name:	Automated fluorescence in situ hybridization (FISH) enumeration system.
Classification:	Class II

G. Intended Use

The GenASIs ScanView System is an automated scanning microscope and image analysis system. It is intended for invitro 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 GenASIs ScanView System is indicated as an accessory to the following FDA cleared/approved devices to detect the following cell types:
1. CEP® X Spectrum Orange™/CEP® Y Spectrum Green™ DNA Probe Kit 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® Path Vysion™ HER-2 DNA Probe kit. Results from the PathVysion™ Kit are intended for use as an adjunct to existing clinical and Pathologic information used as prognostic factors in stage II, node-positive breast cancer patients. The Path Vysion™ kit is further indicated as an aid to predict disease-free and overall survival in patients with stage II, node positive breast cancer, treated with adjuvant cyclophosphamide, doxorubicin, and 5-fluorouracil (CAF) chemotherapy.
3. Cells in urine specimens, stained by fluorescence in situ hybridization (FISH) using Vysis UroVysion™ Bladder Cancer Kit to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus, from persons with hematuria suspected of having bladder cancer. The results are intended for use, in conjunction with and not in lieu of current standard diagnostic procedures, as an aid for initial diagnosis of bladder carcinoma in patients with hematuria and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer.
4. Gene rearrangements involving the ALK gene (2p23) via fluorescence in situ hybridization (FISH) in formalin-fixed paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) tissue specimens, using Vysis® ALK (Anaplastic Lymphoma Kinase) Break Apart FISH Probe kit. The Vysis ALK Break Apart FISH Probe Kit is indicated to aid in identifying those patients eligible for treatment with XALKORI® (crizotinib). The GenASIs ALK System is an accessory to Vysis® ALK (Anaplastic Lymphoma Kinase) Break Apart FISH Probe kit.
The GenASIs ScanView System is to be used as an adjunctive automated enumeration tool in conjunction with manual visualization.

H. Substantial Equivalence Information

1. Comparison of Predicate devices:

#	Comparison parameter	Proposed device: GenASIs ScanView System	Predicate device: ScanView System
1	**510(k) number**	**K122554**	**K110345**
2	**Owner**	**Applied Spectral Imaging Ltd.**	**Applied Spectral Imaging Ltd.**
3	Intended use and indications for use.	The GenASIs 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,	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 as anl

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		intensity, size, pattern; and shape. The GenASIs ScanView System is indicated as an accessory to the following FDA cleared/approved devices to detect the following cell types: 1. CEP® X Spectrum Orange™/CEP® Y Spectrum Green™ DNA Probe Kit 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® Path Vysion™ HER-2 DNA Probe kit. Results from the PathVysion™ Kit are intended for use as an adjunct to existing clinical and Pathologic information used as prognostic factors in stage II, node-positive breast cancer patients. The Path Vysion™ kit is further indicated as an aid to predict disease-free and overall survival in patients with stage II, node positive breast cancer, treated with adjuvant cyclophosphamide, doxorubicin, and 5-fluorouracil (CAF) chemotherapy. 3. Cells in urine specimens, stained by fluorescence in situ hybridization (FISH) using Vysis UroVysion™ Bladder Cancer Kit to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus, from persons with hematuria suspected of having bladder cancer. The results are intended for use, in conjunction with and not in lieu of current standard diagnostic procedures, as an aid for initial diagnosis of bladder carcinoma in patients with hematuria and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer. 4. Gene rearrangements involving the ALK gene (2p23) via fluorescence in situ hybridization (FISH) in formalin-fixed paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) tissue specimens, using Vysis® ALK (Anaplastic	accessory to the following FDA cleared/approved devices to detect the following cell types: 1. CEP® X Spectrum Orange™/CEP® Y Spectrum Green™ DNA Probe Kit and is limited to the analysis of CEP XY probes via high magnification capture and analysis of inrerphase 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® Path Vysion™ HER-2 DNA Probe kit. Results from the PathVysionM Kit are intended for use as an adjunct to existing clinical and pathologic information used as prognostic factors in stage II, node-positive breast cancer patients. The Path VysionT™ kit is further indicated as an aid to predict disease-free and overall survival in patients with stage II, node positive breast cancer, treated with adjuvant cyclophosphamide, doxorubicin, and 5-. fluorouracil (CAF) chemotherapy. 3. Cells in urine specimens, stained by fluorescence in situ hybridization (FISH) using Vysis UroVysion™ Bladder Cancer Kit to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus, from persons with hemnaturia suspected of having bladder cancer. The results are intended for use, in conjunction with and not in lieu of current standard diagnostic procedures, as an aid for initial diagnosis of bladder carcinoma in patients with hemnaturia and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer. The ScanView System is to be used as an adjunctive automated enumeration tool in conjunction with manual visualization.

#	Comparison parameter	Proposed device: GenASIs ScanView System	Predicate device: ScanView System
		Lymphoma Kinase) Break Apart FISH Probe kit. The Vysis ALK Break Apart FISH Probe Kit is indicated to aid in identifying those patients eligible for treatment with XALKORI® (crizotinib). The GenASIs ALK System is an accessory to Vysis® ALK (Anaplastic Lymphoma Kinase) Break Apart FISH Probe kit. The GenASIs ScanView System is to be used as an adjunctive automated enumeration tool in conjunction with manual visualization.	
4	Probe Kit (for GenASIs ALK System)	Vysis® ALK Break Apart FISH Probe Kit (List No. 06N38-020).	Vysis UroVysion™ Bladder Cancer Kit
5	Technical Method	Fluorescence in situ hybridization FISH, an adjunctive automated enumeration tool in conjunction with manual visualization.	Fluorescence in situ hybridization FISH, an adjunctive automated enumeration tool in conjunction with manual visualization.
6	Target Area (for GenASIs ALK System)	Formalin-fixed, paraffin-embedded human non-small cell lung cancer tissue specimen	Cells in urine specimens
7	Image Special Resolution	1280 X 1024 pixels	1280 X 1024 pixels
8	Device Components	Automated microscope, PC, keyboard and control panel, color monitor, CCD Camera, and motorized stage	Automated microscope, PC, keyboard and control panel, color monitor, CCD Camera, and motorized stage
9	Software Version	GenASIs ScanView Version 7.0	ScanView Version 6.0
10	Software Applications	• Control of man-machine Interface. • Scan, Capture, Review and images analysis • Handling the images display, storage and communication. Control of motorized stage.	• Control of man-machine Interface. • Scan, Capture, Review and images analysis • Handling the images display, storage and communication. Control of motorized stage.

2. Substantial Equivalence discussion

Similarities:

Both the proposed GenASIs ScanView system and legally cleared ScanView System (K110345) are platforms for IVD medical devices and laboratory test systems.

Both systems use automated scanning microscope, CCD camera, image analysis software tools, storage media and display monitor 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 proposed GenASIs ScanView system and legally cleared ScanView System (K110345) predicate device are both adjunctive automated enumeration tools for FISH.

Differences:
The legally cleared ScanView System (K110345) is using software version 6.0 while proposed GenASIs ScanView system is using software version 7.0 that includes same applications and tools but has improved features, corrected bugs and is using improved SQL data base for storage (CDM). Additionally the proposed device includes ALK flow capability implemented by using the same FISH and spot counting tools.
The legally cleared ScanView System is for use with Vysis UroVysion™ Bladder Cancer Kit, the proposed GenASIs ScanView system is additionally indicated for using Abbott's FDA approved (P110012) Vysis ALK Break Apart FISH Probe Kit (Vysis ALK Break Apart FISH Probe Kit (List No. 06N38-020)) to detect rearrangements involving the ALK gene (2p23) via fluorescence in situ hybridization (FISH) in formalin-fixed paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) tissue specimens, to aid in identifying those patients eligible for treatment with XALKORI® (crizotinib).

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

The following Special Control and guidance documents are used in the preparation of the 510(K) submission:
1. "Class II Special Controls Guidance Document: Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems" 23 May 2005.

2. Guidance for Industry and FDA Staff: "Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests"; March 2007.

3. "Guidance for the Content of Premarket Submission for Software Contained in Medical Device", CDRH, May 2005.

J. Performance Characteristics

The following information of the device performance characteristics are based on ASI testing and experiments, using the Vysis® ALK™ FISH probe kit. The operators should be aware of the limitations derived from the following performance characteristics:

a. Analytical Performance:

Slides containing formalin-fixed paraffin-embedded (FFPE) tissue specimens from patients with non-small cell lung cancer (NSCLC) were hybridized with the FDA approved Vysis ALK Break Apart FISH Probe Kit according to the manufacturer's instructions.

At each clinical site, archived slides from NSCLC tissue specimens, previously counted and analyzed manually in the last 6 months, were used for the test. Negative cases were selected sequentially from a known bank of negative samples. All positive and equivocal slides that were available during the period of the comparison studies were used for the analysis in

order to have an adequate number of slides in each of the categories.

Patients with NSCLC that were negative for the EGFR test were included in the study. At four clinical sites, a total of 179 slides including 9 cases in the equivocal zone (10-50%) were analyzed. The GenASIs ScanView operator had no prior knowledge of the manual counting results. Method comparison results for all four sites combined are presented below in Table 1:

Table 1: Method Comparison of GenASIs ScanView vs. Manual Method – All sites combined

		Manual Method		
		Negative	Positive	Total
GenASIs ScanView Method	Negative	147	0	147
	Positive	0	32	32
	Total	147	32	179

Overall agreement: 100%% (95% CI: 98%-100%)
Negative percent agreement: 100% (95% CI: 97.5%-100%)
Positive percent agreement: 100% (95% CI: 89.1%-100%)

b. Precision/Reproducibility:

A panel of 10 slides chosen by the manual counting results, 4 of which were negative (<10%), 3 equivocal (10-50%) and 6 positive (>50%) were evaluated for repeatability and reproducibility of diagnosis (positive/negative) for the following:

- **Within-day/within system**: each one of the slides was evaluated three times on the same system on the same day.
- **Between days**: slides were assessed on three separate days on the same system (interval between assessments was at least five days).
- **Between systems**: three GenASIs ScanView ALK Systems were used at three different sites by three different operators.

Diagnoses over different days and systems were 100% concordant for positive vs. negative results, as were within-day results. Both repeatability and reproducibility in the study were 100%.

Mean percent positive cells, standard deviation and % coefficient of variation for each study are presented in Table 2 below. For the negative specimens %CV values are not applicable as a higher degree of variance is to be expected in negative or low positive specimens due to the fewer signals.

Table 2: Repeatability and reproducibility analysis by panel member

Panel Member	% Positive Cells Counted Manually	Within-day/Within-System			Between-Day			Between-System		
		Mean % Positive Cells	SD	% CV	Mean % Positive Cells	SD	% CV	Mean % Positive Cells	SD	% CV
1	61	56.9	4.6	8.0	56.4	3.7	6.7	56.2	3.1	5.5
2	52	46.9	5.9	12.6	47.5	4.3	9.1	46.1	4.4	9.5
3	85	79.6	5.2	6.5	80.0	3.8	4.8	79.4	3.5	4.5
4	0	0.9	1.0	N/A	1.2	0.8	N/A	1.1	0.7	N/A
5	0	1.3	1.3	N/A	0.8	1.1	N/A	1.1	1.1	N/A
6	0	0.6	0.7	N/A	0.5	0.5	N/A	0.7	0.7	N/A
7	0	0.6	1.0	N/A	0.9	0.8	N/A	0.8	0.8	N/A
8	18	22.2	2.9	13.2	25.2	4.8	19.1	24.4	5.0	20.5
9	27	26.7	4.2	15.9	27.8	3.8	13.6	28.3	4.1	14.4
10	31	29.6	5.7	19.2	32.6	6.4	19.6	32.2	5.9	18.2

An additional panel of 5 equivocal specimens around the cutoff (10-25%) were tested for repeatability within-day/within-system. Results are presented in Table 3 below:

Table 3: Within-day/Within Repeatability for specimens around the cutoff

Panel Member	% Positive Cells Counted Manually	Mean% Positive Cells	SD	%CV
1	12	11.6	1.62	13.9
2	19	18.6	1.13	6.0
3	22	19.7	0.6	3.1
4	18	17.6	0.98	5.6
5	19	19.6	1.32	6.7

c. Linearity

Not applicable

d. Carryover:

Not applicable

e. Interfering Substances:

Not applicable

3. Other Supportive Instrument Performance Data Not Covered Above:

Not applicable

K. Proposed Labeling

Labeling was prepared in accordance with the requirements of 21 CFR Part 809.10.

L. Conclusion

Based on the above, it is Applied Spectral Imaging's opinion that the proposed GenASIs System is substantially equivalent in terms of design, principles, and performance characteristics and is shown to be safe & effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 7, 2013

Applied Spectral Imaging Ltd.
Ilan Sharon
P.O.B. 4414 (A-109)
Caesarea 30889, Israel

Re: k122554
Trade/Device Name: GenASIs ScanView System, GenASI ALK System
Regulation Number: 21 CFR 866.4700
Regulation Name: Automated fluorescence *in situ* hybridization (FISH) enumeration systems
Regulatory Class: Class II
Product Code: NTH
Dated: February 6, 2013
Received: February 7, 2013

Dear Mr. Sharon:

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. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Reena Philip-S

for

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122554

Device Name: GenASIs ScanView System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Seena Philip

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) K122554

Indications for Use

510(k) Number (if known): K122554

Device Name: GenASIs ScanView System

Indications for Use: Continued from last page.

3. Cells in urine specimens, stained by fluorescence in situ hybridization (FISH) using Vysis UroVysion™ Bladder Cancer Kit to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus, from persons with hematuria suspected of having bladder cancer. The results are intended for use, in conjunction with and not in lieu of current standard diagnostic procedures, as an aid for initial diagnosis of bladder carcinoma in patients with hematuria and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer.

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Reena Philip

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

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