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

A. 510(k) Number:

K062755

B. Purpose for Submission:

Original 510(k)

C. Manufacturer and Instrument Name:

Ikonisys, Inc. Ikoniscope® oncoFISH™ Bladder Test System

D. Type of Test or Tests Performed:

The Ikoniscope oncoFISH Bladder Test System detects cells of interest from urine samples, stained by FISH using commercially available direct labeled DNA probes or chromosomes 3, 7, 17, and loss of 9p21 locus.

E. System Descriptions:

1. Device Description:

The Ikoniscope onco FISH Bladder Test System is an automated scanning microscope system incorporating automated slide loading and handling, low and high magnification scanning to identify targets of interest and digital image acquisition, coupled with an image analysis workstation. Microscope slides, prepared according to the DNA probe manufacturers' specifications, are placed into a multiple slide cassette, and loaded into the Ikoniscope oncoFISH Bladder Test system. The system unloads each slide, scans each one, and returns it to the cassette automatically. During scanning, images of cells exhibiting the predetermined characteristics for FISH signals are digitally photographed and stored. After all the slides are scanned, the workstation provides an image gallery for each slide that displays the image of each cell meeting predetermined characteristics and quantity and places scanned nuclei into scorable categories, established according to the specifications in the DNA probes FDA cleared labeling. The operator/reader can then evaluate the cell nuclei, and make the diagnostic determination accordingly.

2. Principles of Operation:

The Ikoniscope oncoFISH Bladder Test System combines elements of existing technologies to perform its function. Fluorescence *In-Situ* Hybridization (FISH) uses commercially available, FDA cleared, DNA probes (not supplied with the test system) for labeling chromosomes 3,7,17, and the loss of 9p21 locus (UroVysion® Multicolor DNA Probe Kit, Vysis, Downer's Grove, IL). Automated cell locating/counting using pattern recognition algorithms to identify the signal characteristics of interest. The software incorporated in the system automatically captures an image of each cell containing FISH signals and stores its location on the slide. These images are then presented to the operator, using a computer workstation, for analysis. Images are displayed in scorable categories according to the specifications of the probe developer.

3. Modes of Operation:

N/A

4. Specimen Identification:

Barcode

5. Specimen Sampling and Handling:

Samples should be obtained and handled according to the laboratory's standard operating procedures and following the protocol described in the package insert for the UroVysion probe kit.

6. Calibration:

Calibration of the Ikoniscope is done at the time of installation by Ikonysis.

7. Quality Control:

ProbeChek® quality control slides by Abbott should be used with the UroVysion probes as recommended by the probe manufacturer.

8. Software:

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

Yes____X____ or No_____ Comprehensive software documentation at a Moderate Level of Concern was provided.

F. Regulatory Information:

1. Regulation section:

   21 CFR 864.5260, Automated cell-locating device

2. Classification:

   Class II

3 Product code:

   JOY

4. Panel:

   Hematology (81)

G. Intended Use:

1. Indication(s) for Use:

   The Ikoniscope® *onco***FISH**™ Bladder Test System is an automated scanning microscope coupled with image analysis, acquisition and display functions. It is intended for in-vitro diagnosis as an aide to the technologist or pathologist in the detection, classification and enumeration of cells of interest based on particular characteristics such as intensity, size, shape or fluorescence. The Ikoniscope® *onco***FISH**™ Bladder Test System is intended to detect cells, derived from urine samples, stained by FISH using commercially available direct labeled DNA probes or chromosomes 3, 7, 17 and loss of 9p21 locus. Following identification, a summary report is generated which may provide the basis for a diagnostic determination by the genetics professional and a gallery of the images scanned is presented for review to permit the professional to confirm or deny the diagnosis.

2. Special Conditions for Use Statement(s):

   N/A

H. Substantial Equivalence Information:

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

   BioView, Inc., Duet™ System (K050840)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Illumination	Halogen Lamp	Same
Basic Components	Automated slide loading Automated microscope Camera, PC, Keyboard and control panel, Color monitor, Color printer.	Same Same
Cells Targeted	Urine	Same
Clinical Trial Comparison	Test device compared with standard manual FISH analysis.	Same

Differences		
Item	Device	Predicate
Method of Operation	Automated epifluorescent microscopy with monochrome digital image capture of wave-length specific fluorescent signals.	Automated microscopy in bright-field and fluorescent illumination with color digital image capture of color specific fluorescent signals.
Microscope Objectives	10X, 100X (50X actual resolution).	10X, 60X
Camera	Monochrome, Digital	Color, Digital
Image Presentation	Pseudo-color image	Color image
Clinical Trial Size	100 slides for 100 patients	135 slides for 135 patients

Differences		
Item	Device	Predicate
Intended Use	The Ikoniscop*e*® oncoFISH™ Bladder Test System is an automated scanning microscope coupled with image analysis, acquisition and display functions. It is intended for in-vitro diagnosis as an aide to the technologist or pathologist in the detection, classification and enumeration of cells of interest based on particular characteristics such as intensity, size, shape or fluorescence. The Ikoniscop*e*® oncoFISH™ Bladder Test System is intended to detect cells, derived from urine samples, stained by FISH using commercially available direct labeled DNA probes or chromosomes 3, 7, 17 and loss of 9p21 locus. Following identification, a summary report is generated which may provide the basis for a diagnostic determination by the genetics professional and a gallery of the images scanned is presented for review to permit the professional to confirm or deny the diagnosis.	The Duet™ System is an automated scanning microscope and image analysis system. It is intended for *in-vitro* diagnostic use an aiding tool to the pathologist in the detection, classification and counting of cells of interest based on particular color, intensity, size, shape and pattern. The Duet™ System is intended to detect the following cell types: 1. Hematopoetic cells stained by Giemsa stain, immunohistochemistry or ISH (with bright field or fluorescent) prepared from cell suspension. 2. Amniotic cells stained by FISH (using direct-labeled DNA probed for chromosomes X, Y, 13, 18 and 21. Cells in urine specimens, stained by FISH using the Vysis UroVysion™ Bladder Cancer Recurrence Kit) for chromosomes 3, 7, 17 and 9p21 locus) from subjects with transitional cell carcinoma of the bladder.

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

N/A

J. Performance Characteristics*:*

1. Analytical Performance:

   a. Accuracy:

   The Ikoniscope® *onco***FISH**™ Bladder Test System was evaluated in a clinical trial to determine the accuracy of the system compared with FISH analysis of the same samples using standard manual evaluation. In this trial, results of FISH analysis of 100 patient samples evaluated using the *Ikoniscope® onco*FISH™ Bladder Test System were compared with the results of the evaluation of the same samples using standard manual analysis to perform the FISH analysis. In this trial there was a 99% concordance between the two methods in terms of diagnostic result.

   Results: One hundred consecutive samples were analyzed as the study samples. 96 samples were identical as compared to the manual method. Of the four samples that did not concur, three were read as inconclusive and the manual method identified it as negative. This would indicate a requirement for a manual review of the sample. The oncoFISH Bladder Test system demonstrated a 99% concordance rate.

   b. Precision/Reproducibility:

   A trial, designated the reproducibility trial, tested between system agreement. A total of 50 individual patient slides processed as part of the accuracy study were evaluated on each of two test systems, with the order of the evaluation determined randomly.

   Results: Of the 50 samples analyzed 49 of the samples were concordant. The one slide that was not concordant was a negative and an inconclusive. The most probable reason for this is sample degradation. There was 98 % concordance of diagnostic outcome between the two evaluations for all of the slides

   c. Linearity:

   N/A

d. Carryover:

N/A

e. Interfering Substances:

N/A

2. Other Supportive Instrument Performance Data Not Covered Above:

a. *Comparison of manual dot count with automated dot count.*

The purpose of this study was to demonstrate that oncoFISH dot counting is equivalent to the fastFISH auto/amniocyte dot counting. Two independent-expert cytotechnologists evaluated images of nuclei obtained using the oncoFISH system and compared those results to the results of automated scanning of the same images. The sample consisted of scan data for five slides of which a minimum of 1200 nuclei were to be selected and reviewed.

Results: The study provides evidence that automated scanning, signal recognition and enumeration software produces FISH signal counts that are in agreement with those determined by experienced cytotechnologists that have examined the same images. The overall agreement of the human evaluators and the automated evaluations was 79% and higher for each chromosome signal analyzed.

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.