

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

A. 510(k) Number:

K052577

B. Purpose for Submission:

Original 510(k)

C. Manufacturer and Instrument Name:

Ikonisys, Inc., Ikoniscope™ *fastFISH*™ Amnio Test System

D. Type of Test or Tests Performed:

The Ikoniscope *fastFISH* Amnio Test System detects amniotic cells stained by FISH using commercially available direct labeled DNA probes or chromosomes X, Y, 13, 18, and 21.

E. System Descriptions:

1. Device Description:

The Ikoniscope *fastFISH* Amnio 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 *fastFISH* Amnio 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. The operator/reader can then evaluate the cell nuclei, and make the diagnostic determination accordingly.

2. Principles of Operation:

The Ikonisys *fastFISH* imaging system combines elements of existing technologies to perform its function. Fluorescence In-Situ Hybridization (FISH) uses commercially available DNA probes (not supplied with the test system) for marking chromosomes 13, 18, 12, X and Y. Automated cell locating/counting

uses pattern recognition algorithms to identify the signal characteristics of interest. The Ikoniscope software 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.

3. Modes of Operation:

N/A

4. Specimen Identification:

Barcode

5. Specimen Sampling and Handling:

Amniotic fluid samples should be collected, handled, and prepared according to the protocols for each clinical laboratory. Ikonisys cassettes hold one standard microscope slide.

6. Calibration:

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

7. Quality Control:

ProbeChek® quality control slides provided by Abbott should be used with AneuVysion® 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 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 fastFISH Amnio 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™ Amnio Test System is intended to detect amniotic cells stained by FISH using commercially available direct labeled DNA probes or chromosomes X, Y, 13, 18, and 21.

2. Special Conditions for Use Statement(s):

N/A

H. Substantial Equivalence Information:

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

BioView Ltd., Duet™ System (K001420)

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 for reports	Same
Cells Targeted	Amniocytes	Same

Similarities		
Item	Device	Predicate
Clinical Trial Comparison	Test device compared with standard FISH analysis.	Same

Differences		
Item	Device	Predicate
Method of Operation	Automated epi-fluorescent microscopy with monochrome digital image capture of wavelength 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	124 slides for 62 patients	133 slides for 68 patients
Indications for Use Matrix	Amniotic fluid stained by FISH using direct labeled DNA probes or chromosomes X, Y, 13, 18, and 21.	1. Hematopoietic cells stained by Giemsa stain, immunochemistry or ISH (with brightfield or fluorescent) prepared from cell suspension. 2. Amniotic cells stained by FISH (using direct labeled DNA probes for chromosomes X, Y, 13, 18, and 21.

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

N/A

J. Performance Characteristics:

1. Analytical Performance:

a. *Accuracy:*

The accuracy study was a clinical trial that evaluated samples of amniotic fluid obtained from women undergoing diagnostic amniocentesis. A total of 62 samples (124 slides) were evaluated. Samples were split and prepared for FISH assay in the usual way, using the Vysis Aneu Vysion® probes and following the approved Aneu Vysion protocol. Two sets of slides were prepared from each sample. One set was analyzed using standard manual microscopy and the other using the Ikonisys™ fastFISH™ Amnio Imaging System. Trained cytotechnologists under blind conditions evaluated the samples. The study endpoint was the diagnostic evaluation. There was a 100% concordance of diagnostic results.

b. *Precision/Reproducibility:*

The reproducibility study evaluated possible effects of operator, instrument, or run on the reproducibility of results using the Ikonisys™ fastFISH Amnio Imaging System. Slides for evaluation were prepared by the Sponsor and shipped to the laboratory for testing. Slides for the study were produced using two cultured human amniocyte cell lines. One line has the normal human chromosome complement and the other is trisomic for chromosome 18. Mixtures containing a low (10%) or high (70%) concentration of trisomic cells were prepared from cultures of these lines. Slides containing fixed interphase nuclei were prepared from these specimens following a standard Carnoy fixation protocol. Hybridization of the slides was undertaken at the testing laboratory using the Aneu Vysion™ Kit according to the manufacturer's instructions.

Slide sets were assembled randomly with regard to high and low-concentration samples. Two sets of 10 slides were evaluated on each of four separate instrument runs on different days. Two independent cytotechnologists, who scored the slides in a blind fashion, evaluated the image gallery produced for each slide. Of the 80 slides, 76 were able to be processed. The trial endpoint was the detection of trisomic cells. In only one case was there disagreement between the two independent technologists, yielding an agreement rate of 98.7%. There was no affect of instrument, operator, or run on the reproducibility of the results.

c. *Linearity:*

N/A

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.