

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

A. 510(k) Number:

K061392

B. Purpose for Submission:

Original 510(k).

C. Manufacturer and Instrument Name:

Ikonisys, Inc. Ikoniscope™ *fastFISH*™ Auto/Amniocyte Test System

D. Type of Test or Tests Performed:

The Ikoniscope *fastFISH* Auto/Amniocyte 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* Auto/Amniocyte 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* Auto/Amniocyte 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 a summary of the FISH signals detected for each chromosome of interest and an image gallery that displays the image of each cell nucleus meeting predetermined characteristics and quantity. The operator/reader can then evaluate the condition of the cells and make the diagnostic determination accordingly.

2. Principles of Operation:

The Ikonisys *fastFISH* Auto/Amniocyte Test 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 several sets of images of each nucleus 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:

6. Calibration:

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

7. Quality Control:

ProbeChek® quality control slides 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 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 fastFISH™ Auto/Amniocyte 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. Following fully automated scanning, the system produces a summary report of the frequency of FISH signals detected from each chromosome of interest as a basis for the diagnostic conclusion. The system also provides images of all nuclei scanned for review by the medical professional to confirm the diagnostic conclusion. The Ikoniscope™ Auto/Amniocyte 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:

Ikoniscope fastFISH™ Amnio Test System (K052577)

BioView, Inc., Duet™ System (K001420)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Functional and Operational Basis	Automated epi-fluorescent microscopy with monochrome digital image capture of wave-length specific	fastFISH Auto: Same

Similarities		
Item	Device	Predicate
Illumination:	fluorescent signals. Halogen Lamp	fastFISH Amnio: Same Duet System: Same
Basic Components:	<ul style="list-style-type: none"> • Automated slide loading; • Automated microscope; • Camera; • PC; • Keyboard and control panel; • Color monitor; • Color printer for reports. 	fastFISH Amnio: Same Duet System: Same
Microscope Objectives:	10X, 100X	fastFish Amnio: Same Duet System: 10X, 40X
Cells Targeted:	Amniocytes	fastFISH Amnio: Same Duet System: Same

Differences		
Item	Device	Predicate
Functional and Operational Basis:	Automated epi-fluorescent microscopy with monochrome digital image capture of wave-length specific	Duet System: Automated microscopy in bright-fields and fluorescent illumination with color digital image capture of color specific fluorescent signals.
Camera:	Monochrome, Digital	Duet System: Color, Digital
Scanning Output:	Summary of FISH signals detected. Gallery of nuclei images for professional review.	fastFISH Amnio: Gallery of nuclei images for professional review. Duet System: Gallery of nuclei images for professional review.
Clinical Trial:	262 slides for 131	fastFISH Amnio: 124

Differences		
Item	Device	Predicate
	patients	slides for 62 patients. Duet System: 133 Slides for 68 patients.

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

N/A

J. Performance Characteristics:

1. Analytical Performance:

a. Accuracy:

The purpose of the four-center study was to provide evidence to establish the equivalence of the fastFISH Auto/Amniocyte Test System against scanning by conventional means in the examination of amniocyte slides prepared using FISH. The study included 262 slides from 131 patients. Amniocytes were obtained by amniocentesis from pregnant females scheduled for invasive sampling for karyotyping unrelated to participation in this study.

Results: A diagnostic outcome was reported for 125 of 131 (95%) samples in the test arm of the trial and in 131 of 131 of the samples in the standard/control arm. In the investigational device arm a fully-automated diagnostic outcome was produced for 100 samples (76%) and following review for the remaining 25 samples (19%). Of those samples for which a fully-automated result was obtained, 15 required re-scanning, per the protocol. Diagnostic conclusions determined by the investigational and standard FISH analysis for all 125 samples for which both results were available, was identical for all of the chromosomes examined (X, Y, 13, 18, and 21). The concordance rate for this trial was 100% for those samples for which a comparison was possible.

b. Precision/Reproducibility:

The purpose of the study was to demonstrate the reproducibility of results using the Ikoniscope fastFISH Auto/Amniocyte Test System between systems, operators, and days of operation. All samples were processed and evaluated in a blind fashion. A total of 100 slides were selected from the comparison study.

Results: All slides provided an automated diagnostic outcome and none returned a “review required” outcome. Of the 100 slides, 60 were CEP (Centromeric Probes) and 40 were LSI (Locus specific Probes) slides. All of the CEP slides produced a result for chromosomes X, Y, and 18 based upon 50 nuclei. For the LSI slides, 36 (90%) produced an automated diagnostic outcome based upon 50 nuclei, while in 4 (10%) of LSI slides the diagnostic result was based upon fewer than 50 nuclei, according to the analysis algorithm. This compares to 7% of LSI slides analyzed in the comparison study. This slight increase, which is not statistically significant, could be related to the fact that these slides had been previously scanned possibly resulting in some bleaching of the LSI fluorophores. There was 100% diagnostic concordance for each chromosome (X, Y, 13, 18, and 21).

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.

