JAN 2 4 2006

510(k) Summary
Ikonisys, Inc.

Ikoniscope™ *fastFISH*™ Amnio Test System

510(k) Notification K 052577

GENERAL INFORMATION

Manufacturer:

Ikonisys, Inc.
5 Science Park, Suite 500
New Haven, CT 06511
Phone: 203 776 0791

Contact Person:
S. Michael Sharp, PhD
Vice President
Regulatory and Clinical Affairs

Date Prepared: September 14, 2005

DEVICE INFORMATION

Trade/Proprietary Name: Ikoniscope™ fastFISH™ Amnio Test System

Common/Classification Name: Automated cell-locating device

Classification: 21 CFR 888.3560 – Class II

Device Product Code: JOY

USE OF THE TERM "SUBSTANTIALLY EQUIVALENT"

Any statement regarding Substantial Equivalence made in this submission relates only to the issue of whether or not the device that is the subject of this submission may be lawfully marketed within the United States without Pre-Market Approval or reclassification by the U.S. Food and Drug Administration, and should not be interpreted as an admission, or any other type of evidence, in any patent proceeding, including patent infringement litigation or any proceeding before and Patent Office. The present submission should, therefore, not be construed as affecting or relating to the scope of any patent application or to whether or not the device addressed in the submission, or its use,

may be considered indistinct from a patentability perspective, from any other device, instrument or method referred to in this submission.

PREDICATE DEVICES

The Ikonisys™ fastFISH™ Amnio Imaging System: System is substantially equivalent to FDA-approved predicate devices with regard to indications for use and technological characteristics. The predicate device identified in this submission is: Duet™ (K040591/S1 (BioView, Ltd.)

INTENDED 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™ *fastFISH*™ Amnio Test System is intended to detect amniotic cells stained by FISH using commercially available, FDA approved, direct labeled DNA probes for chromosomes X, Y, 13, 18 and 21.

PRODUCT DESCRIPTION

The Ikoniscope™ *fastFISH*™ Amnio Imaging system is intended to increase the efficiency of current cell analysis methods, by decreasing the amount of time an operator spends scanning slides in search of the cells of interest. The operator/reader identifies chromosome presence by identifying the colors provided by the Fluorescence In Situ Hybridization ("FISH") probes, and manually counts the number of chromosomes appearing within each cell containing such signals.

The Ikoniscope™ *fastFISH*™ Amnio Test System is an automated scanning microscope system incorporating automated slide loading and handing, 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 microscope 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.

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, 21, X and Y.

- Automated Cell Locating/Counting using 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.

Currently, FISH probes are approved for use as adjunct measures to accompany standard cytogenetic analysis of amniocytes, i.e. metaphase cell karytotyping. The Ikoniscope™ *fastFISH*™ Amnio Test System will be used to assist the operator in employing the FISH analysis, and will not change its adjunctive role.

SUBSTANTIAL EQUIVALENCE

Technological Characteristics

The technological characteristics of the Ikoniscope™ *fastFISH*™ Amnio Test System are similar in all essential aspects to those of the cited predicate device. Each of these devices includes a microscope, scanning capability and image display as an adjunct to FISH Analysis by a trained operator or pathologist.

Indications for Use

Substantial equivalence is also supported for the Ikoniscope™ *fastFISH*™ Amnio Test System by the indications for use of the predicate device previously cited and cleared of for use as automated cell-locating devices with similar indications for use.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

The Ikoniscope™ *fastFISH*™ Amnio Test System was evaluated in a clinical trial to determine the accuracy of the system compared with manual FISH analysis. In this trial, results of FISH analysis on split patient samples using the Ikoniscope™ *fastFISH*™ Amnio Test System were compared with the results of standard manual FISH analysis. In this trial there was a 100% concordance between the two methods in terms of diagnostic result. A second trial evaluated the reproducibility of the results produced using the Ikoniscope™ *fastFISH*™ Amnio Test System. This trial demonstrated no variability of results on the basis of operator, instrument or run. These clinical trials provided information that supports a finding of substantial equivalence between the subject device and the cited predicate based on clinical performance when each was compared to the standard method of FISH analysis.

SUMMARY

Based on the similarities in design, function, and intended use, the Ikoniscope™ *fastFISH*™ Amnio Test System is substantially equivalent to the device currently marketed under the Federal Food, Drug and Cosmetic Act. In addition, the Ikoniscope™ *fastFISH*™ Amnio Test System raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ikonisys, Inc.
c/o S. Michael Sharp, Ph.D.
Vice President, Regulatory and Clinical Affairs
5 Science Park, Suite 1000
New Haven, CT 06511

Re: k052577
Trade/Device Name: Ikoniscope™ fastFISH™ Amnio Test System
Regulation Number: 21 CFR 864.5260
Regulation Name: Automated cell-locating device
Regulatory Class: Class II
Product Code: JOY
Dated: November 23, 2005
Received: November 25, 2005

Dear Dr. Sharp:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K

Device Name: Ikoniscope™ *fastFISH*™ Amnio Test System

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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