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510(k) Summary

Ikonisys, Inc.

Ikoniscope™ *fast*FISH™ Auto/Amniocyte Test System

510(k) Notification K 061392

GENERAL INFORMATION

Manufacturer:

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

Contact Person:

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

Date Prepared: May 17, 2006

DEVICE INFORMATION

Trade/Proprietary Name: Ikoniscope™ *fast*FISH™ Auto/Amniocyte 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 any 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 Ikoniscope™ *fast***FISH**™ Auto/Amniocyte Test System is substantially equivalent to FDA-approved predicate devices with regard to regulatory status, indications for use and technological characteristics. The predicate devices identified in this submission are: (1) Ikoniscope™ *fast***FISH**™ Amnio Test System (K052577); (2) BioView Duet™ System (K040591)

INTENDED USE

The Ikoniscope™ *fast***FISH**™ 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™ *fast***FISH**™ Amnio Test System is intended to detect amniotic cells stained by FISH using commercially available directly labeled DNA probes or chromosomes X, Y, 13, 18 and 21.

PRODUCT DESCRIPTION

The Ikoniscope™ *fast***FISH**™ Auto Test 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™ *fast***FISH**™ Auto/Amniocyte 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™ *fast***FISH**™ Auto/Amniocyte Test System microscope system. The system loads each slide on the automated stage, scans, and returns it to the cassette automatically. During scanning, images of cells exhibiting the predetermined characteristics for FISH signals are digitally imaged 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 nucleus meeting predetermined characteristics and quantity. The operator/reader can then evaluate the condition of the cells, and make the diagnostic determination accordingly.

The Ikoniscope™ *fast***FISH**™ 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 identifying chromosomes 13, 18, 21, X and Y.

- Automatic Cell Locating/Counting using 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.

Currently, FISH probes are approved for use as adjunct measures to accompany standard cytogenetic analysis of amniocytes, i.e. metaphase cell karyotyping. The Ikoniscope™ *fast***FISH**™ Auto/Amniocyte 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™ *fast***FISH**™ Auto/Amniocyte Test System are similar in all essential aspects to those of the cited predicate devices. 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™ *fast***FISH**™ Auto/Amniocyte Test System by the predicate devices 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™ *fast***FISH**™ Auto/Amniocyte Test System was evaluated in a clinical trail to determine the accuracy of the system compared with manual FISH analysis. This clinical trial provided information that supports a finding of substantial equivalence between the subject device and the cited predicates based on clinical performance. In addition, a trial to demonstrate the reproducibility of results between systems was also conducted.

SUMMARY

Based on the similarities in design, function, and intended use, the Ikoniscope™ *fast***FISH**™ Auto/Amniocyte Test System is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act and cited in this submission as predicates. In addition, the Ikoniscope™ *fast***FISH**™ Auto/Amniocyte 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

Dr. Petros Tsipouras
CEO
Ikonisys, Inc.
5 Science Park
New Haven, CT 06511

AUG 0 1 2006

Re: k061392
Trade/Device Name: Ikoniscope™ *fast*FISH™ Auto/Amniocyte Test System
Regulation Number: 21 CFR § 864.5260
Regulation Name: Automated cell-locating device
Regulatory Class: II
Product Code: JOY
Dated: May 18, 2006
Received: May 22, 2006

Dear Dr. Tsipouras:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 a 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™ *fast***FISH**™ Auto/Amniocyte Test 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 IF NEEDED)

Josephine Buntella

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061392