510(k) Summary

Ikonisys, Inc.

Ikoniscope® *onco*FISH™ Bladder Test System

510(k) Notification K 062755

JAN - 4 2007

GENERAL INFORMATION

Manufacturer:

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

Contact Person:

Oscar Sanchez
Vice President Quality, Regulatory & Clinical Affairs

Date Prepared: Sept 13, 2006

DEVICE INFORMATION

Trade/Proprietary Name: Ikoniscope® *onco***FISH**™ Bladder Test System

Common/Classification Name: Automated cell-locating device

Classification: 21 CFR 864.5260 – Class II

Device Product Code: 81JOY

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® *onco***FISH**™ Bladder Test System is substantially equivalent to FDA-cleared predicate devices with regard to indications for use and technological characteristics. The predicate devices identified in this submission: (1) Ikoniscope® *fast***FISH**™ Auto/Amniocyte Test System (K052577); (2) BioView Duet™ (K050840)

INTENDED 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.

PRODUCT DESCRIPTION

The Ikoniscope® *onco***FISH**™ Bladder 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® *onco***FISH**™ Bladder 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*® *onco***FISH**™ Bladder 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 nucleus meeting predetermined characteristics and quantity in scorable categories. The operator/reader can then evaluate the cell nuclei, and make the diagnostic determination accordingly.

The Ikonisyscope® *onco***FISH**™ Imaging 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 marking chromosomes 3, 7, 17, and the loss of 9p21 locus.

- Automated Cell Locating/Counting using pattern recognition algorithms to identify the signal characteristics of interest and sort them into scorable categories as defined in the Instructions for Use for the Vysis UroVysion™ DNA Probe Kit.

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 in a gallery that displays cells in scorable categories and stores each image for review by the cytotechnologist, cytogeneticist or pathologist for final diagnostic determination.

Currently, FISH probes are cleared for use as adjunct measures to accompany standard cytogenetic analysis of cells in urine. The Ikoniscope® *onco***FISH**™ Bladder Test System will be used to assist the operator in employing the FISH analysis, and will not change its adjunctive role.

SUBSTANTIAL EQUIVALENCE

Regulatory Characteristics

The regulatory characteristics of the Ikoniscope® *onco***FISH**™ Bladder Test System are identical to those of the predicate devices.

Technological Characteristics

The technological characteristics of the Ikoniscope® *onco***FISH**™ Bladder Test System are similar or identical 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® *onco***FISH**™ Bladder 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® *onco***FISH**™ Bladder Test System was evaluated against the predicate device (K061392) using a Nucleus Specific Accuracy Test (Fish dot counting). The results are similar to those obtained for the Predicate device (#K062755).

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. The reproducibility of the Ikoniscope® scanning process had been confirmed in a 100 sample trial reported in the 510(k) (#K062755) for the predicate device. A second reproducibility trial evaluated the reproducibility of the results produced using the Ikoniscope® *onco***FISH**™ Bladder Test System. This trial demonstrated no variability of results of evaluations performed on the same samples using different instruments. .

A trial, designated the reproducibility trial, tested between system agreement. A total of 50 individual patient slides were evaluated on each of two test systems, with the order of the evaluation determined randomly. There was 98% concordance of diagnostic outcome between the two evaluations for all of the slides. This confirmed the results, reported in K061392, of the reproducibility study of 100 samples evaluated using the Ikoniscope® software package.
These clinical trials provide information that supports a finding of substantial equivalence between the subject device and the cited predicate based on clinical performance

SUMMARY

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

Ikonisys, Inc.
c/o Oscar Sanchez
5 Science Park
New Haven, CT 06511

JAN 0 4 2007

Re: k062755
Trade/Device Name: Ikoniscope® oncoFISH™ Bladder Test System
Regulation Number: 21 CFR 864.5260
Regulation Name: Automated cell locating device
Regulatory Class: Class II
Product Code: JOY
Dated: September 13, 2006
Received: September 14, 2006

Dear Mr. Sanchez:

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 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510(k) Number: K062755

Device Name: Ikoniscope® *onco*FISH™ Bladder 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)

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

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(K) K062755