510(k) Summary

Ikonisys, Inc.

Ikoniscope® oncoFISH® her2 Test System

510(k) Notification k080909

OCT 17 2008

**General Information**

**Manufacturer:**
Ikonisys, Inc.
5 Science Park
New haven, CT 06511
Phone: 203-776-0791

**Contact Person:**
Syed Ataullah
Vice President, Quality Assurance, Regulatory & Clinical Affairs

**Trade/Proprietary Name:** Ikoniscope oncoFISH her2 Test System

**Common/Classification Name:** Automated fluorescent in situ hybridization (FISH) enumeration system

**Classification:** 21CFR 866.4700

**Product code:** NTH

**Panel:** Hematology

**Predicate Device**

The Ikoniscope oncoFISH her2 Test System is substantially equivalent to FDA cleared predicate devices with regard to indications for use and technological charecteristics. The predicate devices identified in this submission: Bioview Duet™ (k050840, k061602) (2) Vysis® AutoVysion™ System - K041875

**Indications for Use Statement**

The Ikoniscope oncoFISH her2 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 oncoFISH her2 Test System is intended to detect and quantify chromosome 17 and the HER-2 gene via fluorescence in situ hybridization (FISH) in interphase nuclei from formalin-fixed, paraffin embedded human breast cancer tissue specimens, probed with the Abbott PathVysion® HER-2 DNA Probe Kit. The Ikoniscope oncoFISH her2 Test System is to be used as an adjunctive automated enumeration tool, in conjunction with manual visualization, to assist in determining Her-2 gene to chromosome 17 signal ratio.

**Intended Use:**

The Ikoniscope oncoFISH her2 Test System is an automated scanning microscope coupled with image analysis, acquisition and display functions. It is intended for in-vitro diagnosis as an aid to the technologist or pathologist in the detection, classification, and enumeration of cells of interest based on the ratio of HER-2 genes to CEP 17 genes. The Ikoniscope oncoFISH her2 Test System is intended to detect amplification of the HER-2/neu Breast gene via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast cancer tissue specimens.

For use only with PathVysion® HER-2 DNA Probe Kit (Abbott Molecular, Inc., Des Plaines, IL)

Product Description:

The Ikoniscope oncoFISH her2 Test System is an automated scanning microscope coupled with image analysis, acquisition, and display functions, which 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. In the manual procedure, the operator/reader identifies gene presence and number by identifying the colors provided by the Fluorescence in situ Hybridization ("FISH") probes, and manually counts the number of genes appearing within each cell containing such signals.

The Ikoniscope oncoFISH her2 Test System incorporates automated slide loading and handling, bright field H&E equivalent image acquisition, low and high magnification scanning to identify targets of interest and digital image acquisition, coupled with an image analysis workstation. The system is capable of imaging an H&E slide and a FISH slide.

The provided desktop scanner supplies an image of the H&E stained slide. By aligning the H&E stained slide with the FISH probed slide, the user can identify which section of the sample they would like the instrument to visit at high magnification. The Ikoniscope system will only visit the selected area at high magnification, greatly decreasing scanning time. Microscope slides, prepared according to the DNA probe (her2/neu PathVysion) manufacturers' specifications are placed into a multiple slide cassette, and loaded into the Ikoniscope oncoFISH® her2 Test System. The system loads 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, and places scanned nuclei into scorable categories, established according the specifications in the DNA probes FDA approved labeling. The operator/reader can then evaluate the cell nuclei, and make the diagnostic determination accordingly. The Ikonisys oncoFISH her2 Test System combines elements of existing technologies to perform its function.

- Fluorescence In-Situ Hybridization (FISH) - uses commercially available, FDA Approved, DNA probes (not supplied with the test system) for labeling the HER-2 gene locus (17q11,2-q12) and for the alpha satellite DNA sequence at the centromeric region of chromosome 17 (17p11.1-q11.1) (PathVysion® HER-2 DNA Probe Kit, Abbott Molecular, Inc., Des Plaines, IL)

- Automated Cell Locating/Counting using pattern recognition algorithms to identify the signal characteristics of interest.

  The software incorporated in the system 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. Images are displayed in scorable categories according to the specifications of the probe developer. Currently, FISH probes are approved by the U.S Food and Drug Administration (FDA) for use as an aid in determining prognosis, and assisting with adriamycin-based chemotherapy selection and Herceptin® (Trastuzumab) monoclonal antibody therapy selection. It is not intended for use in screening for or diagnosing breast cancer. The Ikoniscope oncoFISH her2 Test System will be used to assist the operator in employing the FISH analysis, and will not change its adjunctive role.

  Functional Components:

  The Ikoniscope imaging platform consists of several major components:

- Automated slide loading and unloading, using cassettes
- Automated stage with X, Y, and Z axis positioning
- An epi-fluoresence microscope, with low (4X and 10X) and high (100X) magnification scanning capability
- A monochromatic digital image acquisition camera
- Digitized image storage
- Computer-based workstation, with images displayed in pseudo-color format
- Desktop Scanner

**Technological Characteristics**:

The technological characteristics of the Ikoniscope oncoFISH her2 Test System is 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. Substantial equivalence is also supported for the Ikoniscope oncoFISH her2 Test System by the indications for use of the predicate devices previously cited and cleared for use as automated fluorescent in situ hybridization (FISH) enumeration system with similar indications for use.

**Testing in Support of Substantial Equivalence Determination**

The Ikoniscope oncoFISH her2 Test System was evaluated in a clinical trial to determine the accuracy of the system compared with FISH analysis of the same slides using the standard PathVysion manual enumeration method. The PathVysion slides from four (4) collection sites were tested at two (2) clinical laboratories with two (2) Ikoniscope oncoFISH her 2 systems. A total of 182 slides were enumerated by the PathVysion manual and oncoFISH her2 methods. There was 94.5% (172/182) concordance between the results of the two methods. The 100 PathVysion manual Non-Amplified results had a her2 ratio range of 0.8-1.91. The 104 Ikoniscope oncoFISH her2 Non-Amplified results had a her2 range of 0.75-1.98. The 82 PathVysion manual Amplified results had a her2 ratio range of 2.02-11.3. The 78 Ikoniscope oncoFISH her2 Amplified results had a her2 range of 2.04-7.96.

A reproducibility clinical trial was conducted at each of three (3) clinical sites with the oncoFISH her2 and PathVysion manual methods. Each site tested a sponsor supplied panel of clinical slides for each of three (3) non-consecutive days with both her2 enumeration methods. The reproducibility study allowed each of the three (3) sites to have a total of 18 results for the manual PathVysion and 18 oncoFISH her 2 results. The PathVysion manual reproducibility results had a her2 ratio range of 1.44-2.0; 1.07-1.8; 0.98-1.24; 0.88-1.3; 5.66-12.5 and 1.06-2.5 for the slide panel slides 1, 2, 3, 4, 5 and 6, respectively. The Ikoniscope oncoFISH her2 reproducibility results had a her2 range of 1.37-2.26; 1.14-2.08; 0.96-1.71; 0.76-1.4; 6.19-12.9 and 1.06-2.0. The PathVysion manual Non-Amplified (NA) and Amplified (A) her2 data had 8NA-1A; 9NA; 9NA; 7NA; 9A and 4NA-5A for the slide panel slides 1, 2, 3, 4, 5 and 6, respectively. The Ikoniscope oncoFISH her2 Non-Amplified (NA) and Amplified (A) her2 data had 8NA-1A; 6NA-1A; 9NA; 8NA; 9A and 7NA-1A for the slide panel slides 1, 2,3, 4, 5 and 6, respectively.

Scan to scan variation with the Ikoniscope oncoFISH her2 system was performed at one (1) clinical site. One daily panel of slides was re-scanned two (2) additional times on different days with the Ikoniscope yielding results from three (3) Ikoniscope oncoFISH her2 runs. The means and coefficient of variation (C.V.s) for the three (3) scans of the same six (6) slides were her2 ratio means of 1.63, 1.63, 1.31, 1.45, 10.36, 1.66 and C.V.s of 3.06, 4.79, 6.54, 11.49, 5.49, and 6.00 for panel slides 1, 2, 3, 4, 5, and 6, respectively.

**Summary**:

Based on the similarities in design, function, and intended use, the Ikoniscope oncoFISH her2 Test System is substantially equivalent to devices currently marketed under the Federal, Drug and Cosmetic Act and cited in this submission as predicate devices. In addition, the Ikoniscope oncoFISH her2 Test System raises no safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 17 2008

Ikonisys, Inc.
c/o Mr. Syed Ataullah
Vice President of Quality Assurance, Regulatory, and Clinical Affairs
5 Science Park, Suite 1000
New Haven, CT 06511

Re: k080909
Trade/Device Name: Ikoniscope® oncoFISH™ her2 Test System
Regulation Number: 21 CFR 866.4700
Regulation Name: Automated fluorescent in situ hybridization (FISH) enumeration system
Regulatory Class: Class II
Product Code: NTH
Dated: August 15, 2008
Received: August 18, 2008

Dear Mr. Ataullah:

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

Maria M. Chan

Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): k080909

Device Name: Ikoniscope® oncoFISH® her2 Test System

Indications For Use:

The Ikoniscope® oncoFISH® her2 Test System is an automated scanning microscope coupled with image analysis, acquisition, and display functions. It is intended for in-vitro diagnosis as an aid 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® oncoFISH® her2 Test System is intended to detect and quantify chromosome 17 and the HER-2 gene via fluorescence in situ hybridization (FISH) in interphase nuclei from formalin-fixed, paraffin embedded human breast cancer tissue specimens, probed with the Abbott PathVysion® HER-2 DNA Probe Kit. The Ikoniscope® oncoFISH® her2 Test System is to be used as an adjunctive automated enumeration tool, in conjunction with manual visualization, to assist in determining Her-2 gene to chromosome 17 signal ratio.

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)

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

Reena Philip
...on Sign-Off

...ice of In Vitro Diagnostic Device
...luation and Safety



K080909