JUN 27 2005

K050276

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name: FISHView

Establishment Name and Registration Number of Submitter

Name: Applied Spectral Imaging Ltd.
Registration: 9615060
Submission contact: Dan Laor
Sireni 6, Haifa

Device Classification

Device Code:	LNJ
CFR Section:	864.5260
Name:	Automated cell-locating device.
Classification:	Class II Product

Reason for 510(k) Submission

Traditional 510(k) Submission

Identification of Legally Marketed Equivalent Devices

BANDView system K012103 **Duet system** K040591,

Device Description

The FISHView is a modification of the legally marketed (K012103) BANDView system. Digital visualizing, processing and storage of FISH multi dye images has been added to the BANDView original karyotyping features. The FISHVeiw System is a fully integrated digital imaging platform constructed of a microscope, camera, frame grabber and a workstation. It is designed to acquire images of cells and enables identification and examination of cells of interest. Cytological analysis experts can view, manually scan cells and record the image, using both bright field and fluorescent illumination. The acquire images can be enhanced, archived, retrieved and printed.

Indications for use

The FISHView system is intended to be used for karyotyping with real-time microscope images from cultured and stained cell specimens in their metaphase.
The system works with bright field and fluorescent samples. Specimens suitable for banding analysis are: amniotic fluid, peripheral blood, chorionic villus, bone marrow and solid tumor. Karyotyping is normally applied for the pre and postnatal diagnosis of birth defects, chromosome abnormalities, genetic diseases (such as Down's syndrome), cancer, and for the follow up of cancer treatment. The FISHView system does not locate metaphase spreads; it does not rank the given cells according to quality; nor does it automatically classify chromosomes.

In addition the FISHView is intended as an aiding tool to the pathologist or cytogeneticist for digital visualizing, processing, counting and classification of stained cells and for storage of FISH multi - dye images of the following specimens: amniotic fluid, peripheral blood, chorionic villus, bone marrow and solid tumor.

The FISHView system does require and relies on the operator to analyze the digitized microscope images.

Safety & Effectiveness

The device has been designed verified and validated complying to 21CFR 820.30 regulations. Bench and clinical data demonstrate that the FISHView meets the required specifications. No adverse affects have been detected.

Substantial Equivalency

It is Applied Spectral Imaging opinion that the FISHView is substantially equivalent in terms of safety and effectiveness to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 27 2005

Applied Spectral Imaging, Limited
c/o Mr. Dan Laor
Managing Director
Quasar Quality Limited
Sirni 6 Street
Haifa 32972
Israel

Re: k050236
Trade/Device Name: FISHView
Regulation Number: 21 CFR § 864.5260
Regulation Name: Automated cell-locating device
Regulatory Class: II
Product Code: LNJ
Dated: May 16, 2005
Received: May 19, 2005

Dear Mr. Laor:

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

Indications for Use

510(k) Number (if known): K050236

Device Name: FISHView

Indications For Use: The FISHView system is intended to be used for karyotyping with real-time microscope images from cultured and stained cell specimens in their metaphase. The system works with bright field and fluorescent samples. Specimens suitable for banding analysis are: amniotic fluid, peripheral blood, chorionic villus, bone marrow and solid tumor. Karyotyping is normally applied for the pre and postnatal diagnosis of birth defects, chromosome abnormalities, genetic diseases (such as Down's syndrome), cancer, and for the follow up of cancer treatment. The FISHView system does not locate metaphase spreads; it does not rank the given cells according to quality; nor does it automatically classify chromosomes.

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050236

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)