SEP 1 4 2001

510(K) SUMMARY

BandView system

510(k) Number K01a03

Applicant's Name:

Applied Spectral Imaging Ltd.
P.O.B. 101 Migdal Ha'Emek 10551, Israel
Tel: 972-4-6547567
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Contact Person:

Shoshana Friedman, RAC
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
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Date Prepared:

June, 2001

Trade Name:

BandView system

Classification Name:

Automated cell-locating device

Classification:

The FDA has classified Automated cell-locating device as class II devices (product code 88 LNJ, Regulation No. 864.5260) and they are reviewed by the Pathology Panel.

Predicate Device:

- Ikaros, manufactured by MetaSystems GmbH, cleared under K940240.
- Genevision, manufactured by Applied Imaging Corp. cleared under K902311.

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the BandView system complies with the following voluntary standards:

- EN 55022:1998, Class A;
- EN 55024:1998;
- IEC 61000-4-2:1995
- EN-1441: Medical devices – Risk Analysis.

Indications:

The BandView 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 with all currently applied banding techniques including G-banding and DAPI-banding. All specimens suitable for banding analysis including from amniotic fluid, peripheral blood, chorionic villus, bone marrow, and tissue can be used without limitation to specific diseases. 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 BandView system does not locate metaphase spreads; it does not rank the given cells according to quality; it does not automatically classify chromosomes; it does require and relies completely on the operator to manipulate the digitized microscope images.

Device Description:

The BandView system aids the cytogenetic specialist in the preparation of karyotypes of human cells in their metaphase. By transferring images of chromosome spreads from the microscope to a computer, the labor-intensive manual processing of photographs, data archiving and document preparation is eliminated. Karyotypes are assembled by the operator with the support of the BandView analysis software.

The BandView system does not locate metaphase spreads; it does not rank the given cells according to quality; it does not automatically classify chromosomes; it does require and relies completely on the cytogeneticist to manipulate the digitized microscope images.

Substantial Equivalence:

Applied Spectral Imaging Ltd. believes that the BandView system is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Applied Spectral Imaging, Ltd.
c/o Ms. Shoshanna Friedman, RAC.
Managing Director
Push-med Ltd.
117, Ahuza Street
Ra'ananna 43373, Israel

SEP 1 4 2001

Re: k012103
Trade/Device Name: BandView system
Regulation Number: 21 CFR 864.5260
Regulation Name: Automated cell-locating device
Regulatory Class: Class II
Product Code: LNJ
Dated: June 16, 2001
Received: July 5, 2001

Dear Ms. Shoshanna Friedman:

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 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K012103

Device Name: BandView system

Indications for Use: The BandView 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 with all currently applied banding techniques including G-banding and DAPI-banding. All specimens suitable for banding analysis including from amniotic fluid, peripheral blood, chorionic villus, bone marrow, and tissue can be used without limitation to specific diseases. 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.

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(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012103

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

510(k) Number _____

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)