



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. David G. Davis  
Manager of Regulatory Affairs  
ChromaVision Medical Systems, Inc.  
33171 Paseo Cerveza  
San Juan Capistrano, California 92675-4824

SEP 3 0 2002

Re: k012138  
Trade/Device Name: Automated Cellular Imaging System (ACIS) for detection of  
ER/PR  
Regulation Number: 21 CFR § 864.1860  
Regulation Name: Immunohistochemistry Reagents and Kits  
Regulatory Class: II  
Product Code: MYA, MXZ  
Dated: June 29, 2002  
Received: August 5, 2002

Dear Mr. Davis:

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.

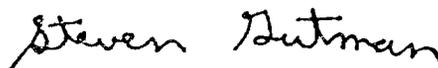
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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

Enclosure

510(k) Number (if known): K012138

Device Name: ACIS

Indications for Use:

The Automated Cellular Imaging System (ACIS) device is intended to detect, count, and classify cells of clinical interest based on recognition of cellular objects of particular color, size, and shape.

In this software application the ACIS device is intended to measure, count, and quantitate the percentage and intensity of positively stained nuclei in formalin-fixed, paraffin-embedded tissue specimens immunohistochemically stained for Estrogen Receptors or Progesterone Receptors (ER/PR).

It is indicated for use as an aid in the management, prognosis and prediction of therapy outcomes of breast cancer.

Deborah M. Moore  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K012138

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_

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