K060227

MAY 25 2006

510(k) SUMMARY

Date Prepared	January 27, 2006
510(k) Number	
Submitter	Vision BioSystems, Inc. 700 Longwater Drive Norwell, MA 02061
Contact	Ron Lagerquist Director, Regulatory Affairs
Device Name	Vision BioSystems Estrogen Receptor Clone 6F11 (ER 6F11)
Common/Usual/ Classification Name	Estrogen Receptor Immunohistochemistry Reagents and Kits
Device Description	ER 6F11 is a monoclonal mouse antibody that detects a human estrogen receptor epitope located in the nucleus of ER positive cells.
Intended Use	ER 6F11 is intended for *in vitro* diagnostic use for the qualitative detection of estrogen receptor in routinely processed tissues. ER 6F11 is indicated as an aid in the management, prognosis and prediction of therapy outcome of breast cancer within the context of the patient's clinical history and other diagnostic tests evaluated by a qualified pathologist.
Substantial Equivalence	ER 6F11 is substantially equivalent to commercially available immunohistochemistry ER antibodies such as Ventana Medical Systems Estrogen Receptor Clone 6F11, and DAKO Corporation Mouse Monoclonal Estrogen Receptor Clone 1D5. ER 6F11 complies with the elements of FDA Guidance, "Guidance for Submission of Immunohistochemistry Applications to the FDA" and, "Guidance for Industry and FDA Staff – Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ronald F. Lagerquist, RAC
Director, Regulatory Affairs
Vision BioSystems, Inc.
700 Longwater Drive
Norwell, MA 02061

MAY 25 2006

Re: k060227
Trade/Device Name: Vision BioSystems Estrogen Receptor Clone 6F11 (ER 6F11)
Regulation Number: 21 CFR § 864.1860
Regulation Name: Immunohistochemistry Reagents and Kits
Regulatory Class: II
Product Code: MYA
Dated: May 11, 2006
Received: May 12, 2006

Dear Mr. Lagerquist:

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

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Device Name:

Vision BioSystems Estrogen Receptor Clone 6F11 (ER 6F11)

- Lyophilized Mouse Monoclonal Antibody
- Liquid Mouse Monoclonal Antibody
- Ready to Use Mouse Monoclonal Antibody
- Origin™ Mouse Monoclonal Antibody

Indications for Use:

Vision BioSystems Estrogen Receptor Clone 6F11 (ER 6F11) Mouse Monoclonal antibody is intended for laboratory use to qualitatively identify by light microscopy, estrogen receptor (ER) antigen in sections of formalin fixed, paraffin embedded tissue. Estrogen Receptor Clone 6F11 specifically binds to the ER antigen located in the nucleus of ER positive normal and neoplastic cells.

ER 6F11 is indicated as an aid in the management, prognosis and prediction of therapy outcome of breast cancer. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

Origin™ antibodies are optimized for use with the Ventana® Medical Systems, NexES® and BenchMark™ Immunohistochemistry Staining Systems in combination with Ventana® Detection Kits.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Josephine Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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