K062615

JAN 29 2007

510(k) SUMMARY

Date Prepared	August 25, 2006
510(k) Number	
Submitter	Vision BioSystems, Inc. 1833 Portola Rd. Ventura, CA 93003
Contact	Ron Lagerquist Director, Regulatory Affairs
Device Name	Vision BioSystems Progesterone Receptor Clone 16
Common/Usual/ Classification Name	Progesterone Receptor Immunohistochemistry Reagents and Kits
Device Description	PGR Clone 16 is a monoclonal mouse antibody that detects a human progesterone receptor epitope located in the nucleus of PGR positive cells.
Intended Use	PGR Clone 16 is intended for *in vitro* diagnostic use for the qualitative detection of progesterone receptor in formalin-fixed paraffin embedded tissues. PGR Clone 16 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	PGR Clone 16 is substantially equivalent to DAKO Corporation Mouse Monoclonal Progesterone Receptor PgR 636

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

VISION Biosystems Inc.
C/O Ronald F. Lagerquist
1833 Portola Road
Ventura, California 93003

JAN 2 9 2007

Re: k062615
Trade/Device Name: Vision BioSystems Progesterone Receptor Clone 16
Regulation Number: 21 CFR 864.1860
Regulation Name: Immunohistochemistry Reagents and Kits
Regulatory Class: Class II
Product Code: MXZ
Dated: August 25, 2006
Received: September 5, 2006

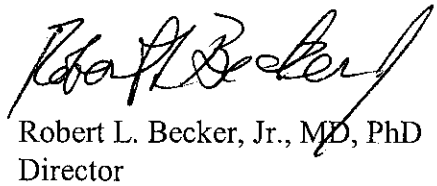
Dear Mr. Lagerquist:
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate 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 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 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 Compliance at (240) 276-0450. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC

HFZ-404 510(k) Staff
HFZ- 440 Division
D.O.

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Indications for Use

510(k) Number K062615

Device Name:

Vision BioSystems Progesterone Receptor Clone 16 (PGR Clone16)

- Novocastra™ Lyophilized Mouse Monoclonal Antibody
- Novocastra™ Liquid Mouse Monoclonal Antibody
- Novocastra™ Ready-to-Use Primary Antibody
- Origin™ Ready-to-Use Primary Antibody
- Bond™ Ready-to-Use Primary Antibody

Indications for Use:

Vision BioSystems Progesterone Receptor Clone 16 (PGR Clone 16) Mouse Monoclonal antibody is intended for laboratory use to qualitatively identify by light microscopy, progesterone receptor (PGR) antigen in sections of formalin fixed, paraffin embedded tissue. PGR Clone 16 specifically binds to the PGR antigen located in the nucleus of PGR positive normal and neoplastic cells.

PGR Clone 16 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.

Novocastra™ antibodies are intended for manual use. Origin™ antibodies are optimized for use with the Ventana® Medical Systems, NexES® and BenchMark™ Immunohistochemistry Staining Systems in combination with Ventana® Detection Kits. Bond™ Ready-to-Use Primary Antibodies are optimized for use on the Vision BioSystems Bond-max™ system.

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)

Division Sign-Off Concurrence of CDRH, Office of Device Evaluation (ODE)

Office of In Vitro Diagnostic Device Evaluation and Safety

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