FEB 15 2005

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K042884

Submitter:	DakoCytomation California, Inc. 6392 Via Real Carpinteria, CA 93013 PH. 805.566.6655 FX. 805.566.0866 Establishment registration number: 2022180
Contact:	Tiffany D. Almeroth, RAC Sr. Regulatory Affairs Specialist PH. 805.566.3041
Date Summary Prepared:	September 30, 2004
Device Name(s):	DakoCytomation ER/PR pharmDx™ Kit. Immunohistochemistry kit. (Code K1903/K1904) DakoCytomation Monoclonal Mouse Anti-Human Progesterone Receptor, clone PgR 1294. Antibody for immunoenzymatic staining. (Code M3568)
Device Classification:	Class II, for prognostic immunohistochemical staining reagents. 21 CFR 864.1860
Panel:	Hematology and Pathology Devices Panel Division of Clinical Laboratory Devices.
Predicate Devices:	Estrogen Receptor • DakoCytomation Monoclonal Mouse Anti-Human Estrogen Receptor, Clone 1D5, (K993957) • Ventana ER clone 6F11, (K984567) Progesterone Receptor • DakoCytomation Monoclonal Mouse Anti-Human Progesterone Receptor, Clone PgR 636, (K020023)

Device Description:

The DakoCytomation ER/PR pharmDx™ assay is a semi-quantitative immunohistochemical (IHC) kit system to identify estrogen receptor (ER) and progesterone receptor (PR) expression in normal and neoplastic tissues routinely processed and paraffin-embedded for histological expressing cells respectively.
ER/PR pharmDx assay is available in two configurations, both manual and automated and is optimized for use with DakoCytomation detection systems.

The DakoCytomation Monoclonal Mouse Anti-Human Progesterone Receptor, clone PgR 1294, is a component of the ER/PR pharmDx kit, which will also be commercially available as a concentrate.

Intended Use:

For *In Vitro* Diagnostic Use
The DakoCytomation ER/PR pharmDx™ assay is an immunohistochemical (IHC) kit system to identify human estrogen receptor (ER) and human progesterone receptor (PR) expression in breast cancer tissues routinely processed and paraffin-embedded for histological evaluation. ER/PR pharmDx specifically detects the ER alpha protein as well as the PR located in the cell nucleus of ER and/or PR-expressing cells.

ER/PR pharmDx is indicated as an aid in identifying patients eligible for treatment with anti-hormonal or aromatase inhibitor therapies, as well as an aid in the prognosis and management of breast cancer.

The DakoCytomation Monoclonal Mouse Anti-Human Progesterone Receptor, clone PgR 1294, is intended for laboratory use as a semi-quantitative detection of progesterone receptor by light microscopy in routinely processed normal and pathological human paraffin-embedded tissue. This antibody is indicated for use as an aid in the management, prognosis and prediction of outcome of breast cancer. The clinical interpretation of any positive staining or its absence should be complemented by morphological and histological studies with proper controls. Evaluations should be made within the context of the patient's clinical history and other diagnostic tests by a qualified individual

Substantial Equivalence:

The DakoCytomation anti-estrogen receptor reagent cocktail, clones 1D5 and ER-2-123, is substantially equivalent to the Ventana ER clone 6F11 and DakoCytomation monoclonal mouse anti-human ER, clone 1D5 in that these products specifically bind to estrogen receptor proteins located in the nuclei of cells. These products require similar detection chemistry principles for visualization of the product, and both aid in the prognosis of breast carcinoma. The difference in visualization does not introduce new issues of safety and effectiveness.

The DakoCytomation PgR 1294 antibody is substantially equivalent to the DakoCytomation PgR 636 antibody, in that these products both bind to progesterone receptor proteins located in the nuclei of breast cancer cells, and use similar detection chemistry principles for visualization.

Performance Characteristics:

Performance characteristics evaluated in support of the ER/PR pharmDx™ IHC kit and components include results on specificity, sensitivity, reproducibility, and concordance testing. Results of all testing conducted have demonstrated a substantial degree of equivalency to the predicate devices listed above. Further, concordance testing between the DakoCytomation ER/PR pharmDx kit and the reference, Allred method, demonstrated

substantially equivalent staining results (99% concordance).

Therefore, based on the information provided in this premarket notification, DakoCytomation concludes that the devices listed above are safe, effective and substantially equivalent to their respective predicate devices in their indications for use, device design, materials, operational principles, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 15 2005

Ms. Tiffany D. Almeroth, RAC
Senior, Regulatory Affairs Specialist
DakoCytomation California, Inc.
6392 Via Real
Carpinteria, California 93013

Re: k042884
Trade/Device Name: DakoCytomation ER/PR pharmDx™ Kit
Regulation Number: 21 CFR § 864.1860
Regulation Name: Immunohistochemistry Reagents and Kits
Regulatory Class: II
Product Code: MYA, MXZ
Dated: January 3, 2005
Received: January 6, 2005

Dear Ms. Almeroth:

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

510(k) Number (if known): K042884

Device Name: Monoclonal Mouse Anti-Human Progesterone Receptor, Clone: PgR 1294 (DakoCytomation Code No. M3568)

Indications For Use:

The DakoCytomation Monoclonal Mouse Anti-Human Progesterone Receptor, clone PgR 1294, is intended for laboratory use as a semi-quantitative detection of progesterone receptor by light microscopy in routinely processed normal and pathological human paraffin-embedded tissue. This antibody is indicated for use as an aid in the management, prognosis and prediction of outcome of breast cancer. The clinical interpretation of any positive staining or its absence should be complemented by morphological and histological studies with proper controls. Evaluations should be made within the context of the patient's clinical history and other diagnostic tests by a qualified individual.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use**____

(Per 21 CFR 801.109) (Per 21 CFR 801.110

IVD Use____

(Per 21 CFR 801.119

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042884

(Optional Format 1-2-96)

510(k) Number (if known): K042884

Device Name: DakoCytomation ER/PR pharmDx™
(DakoCytomation Code No. K1903)

Indications For Use:

The DakoCytomation ER/PR pharmDx™ assay is a semi-quantitative immunohistochemical (IHC) kit system to identify estrogen receptor (ER) and progesterone receptor (PR) expression in normal and neoplastic tissues routinely processed and paraffin-embedded for histological evaluation. ER/PR pharmDx specifically detects the ER alpha protein as well as the PR protein located in the cell nucleus of ER and PR-expressing cells respectively.

ER/PR pharmDx is indicated as an aid in identifying patients eligible for treatment with anti-hormonal or aromatase inhibitor therapies, as well as an aid in the prognosis and management of breast cancer.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use**____
(Per 21 CFR 801.109) (Per 21 CFR 801.110

IVD Use____
(Per 21 CFR 801.119

(Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K042884