MAY - 8 2009

510(k) Summary

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

The assigned 510(k) number is: K081286

Submitter:	Dako North America, Inc. 6392 Via Real Carpinteria, CA 93013 PH. 805.566.6655 FX. 805.566.0866 Establishment registration number: 2022180
Contact:	Kelly Miller Manager, Regulatory Affairs PH. 805.566.6655 ext. 5330 Fax: 805.566.0866
Date Summary Prepared:	April 8, 2009
Device Name(s):	Monoclonal Rabbit Anti-Human Estrogen Receptor α antibody, Clone SP1 (Code M3634)
Device Classification:	Class II (21 CFR 864.1860)
Predicate Device:	Monoclonal Mouse ER 1D5/ER-2-123 in the Dako ER/PR pharmDx™ Kit (K042884)

Device Description:

Dako Monoclonal Rabbit Anti-Human Estrogen Receptor α antibody, Clone SP1 is a semi-quantitative immunohistochemical (IHC) kit assay to identify estrogen receptor (ER) expression in normal and neoplastic tissues routinely processed and paraffin-embedded.

Intended Use:

For in vitro diagnostic use.

Monoclonal Rabbit Anti-Human Estrogen Receptor α (ER α) antibody, Clone SP1, may be used in the semi-quantitative detection of human estrogen receptor in formalin-fixed, paraffin-embedded tissue sections of human breast cancer by immunohistochemistry. The information gained by this assay can aid in assessing the likelihood of response to therapy as well as in the prognosis and management of breast cancer patients.

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 pahtologist.

Substantial Equivalence:
Dako Estrogen Receptor Clone SP1 immunohistochemical assay is substantially equivalent to Monoclonal Mouse ER 1D5/ER-2-123 in the Dako ER/PR pharmDx™ Kit. Both 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.

Performance Characteristics:
Performance characteristics evaluated for the Estrogen Receptor Clone SP1 IHC assay include results on analytical specificity and sensitivity, precision, reproducibility and method comparison testing. Results of all testing conducted substantial equivalence to the predicate device listed above.

Based on the information provided in this premarket notification, Dako concludes that Monoclonal Rabbit Anti-Estrogen Receptor α, Clone SP1 is substantially equivalent to the predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 8 2009

Dako North America, Inc.
c/o Kelly Miller
Manager RA
6392 Via Real
Carpinteria, CA 93013

Re: k081286
Trade/Device Name: Dako Monoclonal Rabbit Anti-Human Estrogen Receptor, Clone SP1
Regulation Number: 21 CFR 864.1860
Regulation Name: Immunohistochemistry reagents and kits
Regulatory Class: Class II
Product Code: MYA
Dated: May 4, 2009
Received: May 5, 2009

Dear Ms. Miller:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Maria M Chan

Maria Chan, PhD
Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K081286

Device Name: Dako Monoclonal Rabbit Estrogen Receptor α, Clone SP1

Indications For Use:

For in vitro diagnostic use.

Monoclonal Rabbit Anti-Human Estrogen Receptor α (ER α) antibody, Clone SP1, may be used in the semi-quantitative detection of human estrogen receptor in formalin-fixed, paraffin-embedded tissue sections of human breast cancer by immunohistochemistry. The information gained by this assay can aid in assessing the likelihood of response to therapy as well as in the prognosis and management of breast cancer patients.

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 pathologist.

(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

Maria M Chan
Division Sign-Off

Over-The-Counter Use___
(Per 21 CFR 801.110)

IVD Use ✓
(Per 21 CFR 801.119)

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K081286