

December 07, 2018

Zhijun (Julie) Pan, MD, PhD, RAC
Manager, Regulatory Affairs and Submissions
Leica Biosystems
38 Cherry Hill Drive
Danvers, MA 01923

Re: K183100

Trade/Device Name: Estrogen Receptor Clone 6F11 (ER 6F11)

- Estrogen Receptor Clone 6F11 Ready-to-Use Primary Antibody for Bond™;
- Estrogen Receptor Clone 6F11 Liquid Concentrate Primary Antibody, Novocastra™

Regulation Number: 21 CFR 864.1860

Regulation Name: Immunohistochemistry reagents and kits

Regulatory Class: Class II

Product Code: MYA

Dated: November 3, 2018

Received: November 7, 2018

Dear Dr. Zhijun (Julie) Pan:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Soma Ghosh -S
2018.12.07 15:36:17 -05'00'
11.0.22

for

Reena Philip, Ph.D.
Director
Division of Molecular Genetics and Pathology
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known)

K183100

Device Name

Estrogen Receptor Clone 6F11 (ER 6F11)

- Estrogen Receptor Clone 6F11 Ready-to-Use Primary Antibody for Bond™;
- Estrogen Receptor Clone 6F11 Liquid Concentrate Primary Antibody, Novocastra™

Indications for Use (Describe)

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

Estrogen Receptor Clone 6F11 is indicated as an aid in the management, prognosis and predication 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.

Estrogen Receptor Clone 6F11 Ready-to-Use Primary Antibody for Bond™ and the Estrogen Receptor Clone 6F11 Liquid Concentrate Primary Antibody, Novocastra™ are optimized for use on the Leica Biosystems Bond III staining platform using the Bond Polymer Refine Detection Kit.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."