December 21, 2017

Dako Denmark A/S
Lasse Post Møller
Pathology Regulatory Affairs Manager
Produktionsvej 42
DK-2600 Glostrup, Denmark

Re: K170028
Trade/Device Name: FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use (Dako Omnis)
Regulation Number: 21 CFR 864.1860
Regulation Name: Immunohistochemistry reagents and kits
Regulatory Class: Class II
Product Code: MYA
Dated: December 28, 2017
Received: January 3, 2017

Dear Lasse Post Møller:

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); 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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Reena Philip -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170028

Device Name
FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use (Dako Omnis)

Indications for Use *(Describe)*
For in vitro diagnostic use.
FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use (Dako Omnis), is intended for use in immunohistochemistry with the EnVision FLEX visualization system together with the Dako Omnis instrument to qualitatively detect human estrogen receptor in formalin-fixed, paraffin-embedded tissue sections of human breast cancer. The antibody binds estrogen receptor α expressing cells and is useful in the assessment of estrogen receptor status in human breast carcinomas.
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. This antibody is intended to be used after the primary diagnosis of tumor has been made by conventional histopathology using nonimmunologic histochemical stains.

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.

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5. 510(k) Summary

Traditional Premarket Notification Submission (510(k)) Summary
Prepared in accordance with 21 CFR 807.92

Sponsor Name and Address

Dako Denmark A/S
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2600 Glostrup, Denmark

Establishment registration No: 9610099

Contact

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Date Summary Prepared

December 21, 2017

Device Name(s)

Trade name(s)	FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use (Dako Omnis)
Product code:	GA084
Common name	Anti-Human ER a, Clone EP1 (Dako Omnis)
Classification:	Class II (21 CFR 864.1860)
FDA Product Code:	MYA

Predicate Device:

Trade name (s):	Dako Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, FLEX, Ready-to-Use (RTU) Link
FDA Product code:	MYA
Classification:	Class II (21 CFR 864.1860)
Device	Cleared in Premarket notification K120663.

Device Description

The FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use (Dako Omnis) antibody is utilized to perform a qualitative immunohistochemical (IHC) assay to identify estrogen receptor (ER) expression in formalin fixed human breast cancer tissues routinely processed and paraffin-embedded for histological examination.

The design of the proposed device is based on the design of its predicate FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use (Link) with adaptation of the product configuration, to be used on the Dako Omnis Instrument instead of the Autostainer Link 48 Instrument.

The antibody is provided in liquid form in a buffer containing stabilizing protein and 0.015 mol/L sodium azide. The antibody is intended for automated immunohistochemical (IHC) slide staining with the Dako Omnis Instrument and the software performing and controlling the automated slide staining process is validated for its intended use.

Intended Use:

For in vitro diagnostic use.

FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use (Dako Omnis), is intended for use in immunohistochemistry with the EnVision FLEX visualization system together with the Dako Omnis instrument to qualitatively detect human estrogen receptor in formalin-fixed, paraffin-embedded tissue sections of human breast cancer. The antibody binds estrogen receptor α expressing cells and is useful in the assessment of estrogen receptor status in human breast carcinomas.

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. This antibody is intended to be used after the primary diagnosis of tumor has been made by conventional histopathology using nonimmunologic histochemical stains.

Substantial Equivalence

The proposed device, FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use (Dako Omnis), is claimed to be substantially equivalent to the predicate device FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use (Link), also referred to by its product code IR084. The predicate device is cleared for the US market in the premarket notification K120663.

Both products specifically bind to estrogen receptor (ER) proteins located in the nuclei of cells. Both products require similar detection chemistry principles for visualization of antigens, and both aid in the prognosis of breast carcinoma. Both products have the same intended use, staining steps and scoring guideline for interpretation.

All differences between the proposed device GA084 and its predicate are related to their use with different slide staining instruments, see details in the comparison table below.

Similarities		
Item	**Device**	**Predicate**
Intended Use	Detection of Estrogen Receptor α Protein	same
Antibody Type	Monoclonal, rabbit origin	Same
Isotype	IgG	Same
Clone	EP1	Same
Staining Pattern	Nuclear	Same
Interpretation of results	Positive: ≥1% positive staining breast cancer cells	Same

Similarities		
Item	**Device**	**Predicate**
Tissue Type	Formalin-fixed paraffin-embedded breast cancer	Same
Technology	Immunohistochemistry	Same
Storage	2-8 °C	Same

Differences		
Item	**Device**	**Predicate**
Configuration	Pre-diluted Ready-to-use with Dako Omnis	Pre-diluted Ready-to-use with Autostainer Link 48
Temperature Control/Incubation Temperature	Temperature controlled at 32°C ± 2°C	No temperature control (ambient temperature)
Antibody Concentration	15 µg/mL	3.7 µg/mL
Antibody Incubation Time	10 minutes	20 minutes
Staining	Dynamic gap staining: Reagent is applied and distributed across slide via active slide lids which enable capillary force spreading	Open slide staining: Reagent is applied and distributed across slide via gravitational spreading
Vial	Dako Omnis Large Vial, 30 mL	Automation Vial, 25mL
Cap	Dako Omnis Closure including septum	White Nalgene Cap
Deparaffinization	On-board Dako Omnis with Clearify	EnVision FLEX High pH on external PT Module
Pre-Treatment (Antigen Retrieval)	EnVision FLEX High pH (30 minute heat-induced Epitope retrieval)	EnVision FLEX High pH (20 minute heat-induced Epitope retrieval)
Visualization	EnVision FLEX (Chromogen 5 minutes)	EnVision FLEX (Chromogen 2 x 5 minutes)

The proposed device is evaluated to be substantially equivalent to its predicate device and does not introduce any new issues for safety and effectiveness.

Performance Characteristics

Performance characteristics were evaluated to determine its analytical specificity for normal tissue and reproducibility to control intra run, inter run, inter lot, inter-laboratory and inter-observer variations. The device was also evaluated in a concordance study to establish equivalence to the predicate device. All results from performance studies confirm that

GA084 meets its acceptance criteria and is substantial equivalent to its predicate device IR084.

Therefore, based on the information provided in this premarket notification, we conclude that, FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use (Dako Omnis) is safe, effective and substantially equivalent to the predicate device in the indication for use, device design, materials, operational principles, and intended use.