SPECIAL 510(K): DEVICE MODIFICATION
OIR DECISION MEMORANDUM

510(k) Number: ____K183102_____

This 510(k) submission contains information/data on modifications made to the applicant's own class II or class I devices requiring 510(k). The following items are present and acceptable:

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1. The name and 510(k) number of the applicant's previously cleared device.

   K171753: BOND™ Ready-to-Use (RTU) Primary Antibody Progesterone Receptor (16) and Concentrated Liquid Mouse Monoclonal Antibody (Novocastra™)

2. Applicant's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This change was for

   - Replacement of the slide staining assembly (SSA) printed wiring assembly (PWA) and its associated embedded firmware due to microprocessor obsolescence,
   - BOND software update from version 5.1 to 6.0.

   No changes have been made to the BOND IHC F protocol that is used on the BOND MAX instrument and no change has been made to the reagent for the BOND Ready-to-Use (RTU) Primary Antibody Progesterone Receptor (16) and Concentrated Liquid Mouse Monoclonal Antibody (Novocastra™) assay.

   The BOND IHC F protocol has been verified to remain consistent by (a) not changing the data supplied to the BOND Application and (b) showing that the data passed to the instrument remains identical to that under the previous approved software releases versions 4.1, 5.0 and 5.1.

   Verification and validation activities are performed for every change to BOND Ready-to-Use (RTU) Primary Antibody Progesterone Receptor (16) and the BOND-MAX instrument. The verification and validation procedures, methods and acceptance criteria for product changes remain the same as those performed for the predicate device, K171753.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including device name, intended use, physical characteristics, quality control and antibody manufacturing, labeling as well as software, are in the table below.

Item	K183102 (Subject Device)	K171753 (Predicate Device)
Device Name	BOND™ Ready-to-Use (RTU) Primary Antibody Progesterone Receptor (16) and Concentrated Liquid Mouse Monoclonal Antibody (Novocastra™)	Same
Intended Use / Indications for Use	Ready-to-Use Format Progesterone Receptor (16) monoclonal antibody is intended to be used for the qualitative identification by light microscopy of human progesterone receptor (PR) in formalin-fixed, paraffin-embedded tissue by immunohistochemical staining using the automated BOND-MAX system. Progesterone Receptor Clone (16) [PR (16)] specifically binds to the PR antigen located in the nucleus of PR positive normal and neoplastic cells. PR (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. Concentrated Liquid Antibody Format. Progesterone Receptor (PGR) Clone 16 monoclonal antibody is intended to be used for the qualitative identification by light microscopy of human progesterone receptor in formalin-fixed, paraffin-embedded tissue by immunohistochemical staining. 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.	Same
RTU Reagent	Progesterone Receptor (16) is a mouse anti-human monoclonal antibody produced as a tissue culture supernatant, and supplied in Tris buffered saline with carrier protein, containing 0.35% ProClin™ 950 as a preservative.	Same

	Total Volume = 7 mL Total Protein Concentration: 10 mg/mL Antibody Concentration: ≥ 1 mg/L	
Concentrated AB Reagent	NCL-L-PGR-312 is a liquid tissue culture supernatant containing 15 mM sodium azide as a preservative. Total Protein Concentration: Batch Specific	Same
Clone, Immunogen, Specificity, Subclass (both formats)	Clone: 16 Immunogen: Prokaryotic recombinant protein corresponding to the N-terminal region of the A form of the human progesterone receptor Specificity: Human progesterone receptor Subclass: IgG1	Same
Technology	Immunohistochemistry	Same
Tissue Type	formalin-fixed, paraffin-embedded breast cancer tissue	Same
Staining Pattern	Nuclear	Same
Platform	RTU: BOND-MAX	Same
Staining Protocol	BOND IHC F	Same
Slide Staining Assembly (SSA) Printed Wiring Assembly (PWA)	Replacement of the SSA PWA and its associated embedded firmware due to microprocessor obsolescence	Original SSA / PWA
BOND Software	Version 6.0	Version 5.1

5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

Risk assessments for the SSA PWA changes and BOND software v5.1 to v6.0 changes were performed to assess the impact of the modifications on the device by identifying risks, their possible causes, and appropriate control mechanisms. The Risk Analyses took into account device hazards associated with the intended use of the device. No additional hazards, no additional causes, and no required additional controls were identified. No adverse events or reportable incidents have been associated with the device.

The following studies were performed to verify and validate for the SSA PWA changes:

- Staining Verification and Validation
- EMC Testing
- Overall Hardware and Software Verification
    - Hardware Progression Verification
    - Firmware Progression Verification
    - System Integration Verification
    - System Regression Verification
    - Upgrade Utility Verification

The following studies were performed to verify and validate for the update of BOND software from v5.1 to v6.0:

- Staining Verification and Validation
- Software Verification

For each test, acceptance criteria were identified and observed results were compared to expected results. All acceptance criteria were met and all tests passed.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the applicant's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The applicant has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.